Anhang 4-G: Ergänzende Daten zu den in Abschnitt 4.3.1.3 gezeigten Ergebnissen für die Studie RATIONALE 306

Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Number of Patients Randomized	13 (100.0)	17 (100.0)	30 (100.0)
Patients Randomized, But not Treated	0 (0.0)	0 (0.0)	0 (0.0)
Primary Reason for not Treated [a]			
Number of Patients Treated	13 (100.0)	17 (100.0)	30 (100.0)
Number of Patients Discontinued from Treatment	10 (76.9)	15 (88.2)	25 (83.3)

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
[a] Patients randomized but not treated with any treatment component.
[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.
[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.
[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.
[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Drug Discontinuation [b]			
Progressive Disease	7 (53.8)	12 (70.6)	19 (63.3)
Radiographic Progression	6 (46.2)	11 (64.7)	17 (56.7)
Clinical Progression	1 (7.7)	1 (5.9)	2 (6.7)
Adverse Event	1 (7.7)	2 (11.8)	3 (10.0)
Treatment-interruption [c]	1 (7.7)	0 (0.0)	1 (3.3)
Withdrawal by Subject	1 (7.7)	1 (5.9)	2 (6.7)
Number of Patients Remained on Treatment	3 (23.1)	2 (11.8)	5 (16.7)
Number of Patients Discontinued from Study	4 (30.8)	12 (70.6)	16 (53.3)

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Discontinuation			
Death	4 (30.8)	10 (58.8)	14 (46.7)
Lost to Follow-up	0 (0.0)	1 (5.9)	1 (3.3)
Withdrawal by Subject	0 (0.0)	1 (5.9)	1 (3.3)
Number of Patients Remained on Study	9 (69.2)	5 (29.4)	14 (46.7)
Study Follow-up Duration [d] (months)			
n	13	17	30
Mean (SD)	19.8 (7.79)	13.0 (8.74)	16.0 (8.90)
Median	19.6	9.8	18.5
Q1, Q3	18.2, 24.8	7.0, 19.1	8.0, 23.8
Min, Max	1.8, 30.1	2.2, 30.3	1.8, 30.3

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Minimum Study Follow-Up Time [e] (months)	18.2	17.5	17.5

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Age (years)			
n	13	17	30
Mean (SD)	59.7 (7.48)	65.1 (7.94)	62.8 (8.08)
Median	60.0	66.0	62.5
Q1, Q3	57.0, 65.0	59.0, 72.0	58.0, 69.0
Min, Max	46, 69	47, 76	46, 76
Age Group, n (%)			
< 65 years	9 (69.2)	8 (47.1)	17 (56.7)
≥ 65 years	4 (30.8)	9 (52.9)	13 (43.3)
Sex, n (%)			
Female	4 (30.8)	6 (35.3)	10 (33.3)
Male	9 (69.2)	11 (64.7)	20 (66.7)
Region, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Asia (excluding Japan)	6 (46.2)	2 (11.8)	8 (26.7)
Japan	5 (38.5)	9 (52.9)	14 (46.7)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Race, n (%)			
Asian	11 (84.6)	11 (64.7)	22 (73.3)
Chinese	5 (38.5)	1 (5.9)	6 (20.0)
Japanese	5 (38.5)	9 (52.9)	14 (46.7)
Korean	1 (7.7)	1 (5.9)	2 (6.7)
White	2 (15.4)	5 (29.4)	7 (23.3)
American Indian or Alaska Native	0 (0.0)	1 (5.9)	1 (3.3)
Ethnicity, n (%)			
Hispanic or Latino	0 (0.0)	1 (5.9)	1 (3.3)
Not Hispanic or Latino	13 (100.0)	16 (94.1)	29 (96.7)
ECOG Status, n (%)			
0	7 (53.8)	10 (58.8)	17 (56.7)
1	6 (46.2)	7 (41.2)	13 (43.3)

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
BMI (kg/m^2)			
n	13	17	30
Mean (SD)	21.92 (3.553)	21.20 (3.497)	21.51 (3.479)
Median	21.63	20.91	21.40
Q1, Q3	21.10, 22.86	19.20, 23.31	20.20, 23.31
Min, Max	14.3, 28.3	15.9, 29.2	14.3, 29.2
Tobacco Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	9 (69.2)	12 (70.6)	21 (70.0)
Current	1 (7.7)	1 (5.9)	2 (6.7)
Alcohol Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	8 (61.5)	10 (58.8)	18 (60.0)
Current	2 (15.4)	2 (11.8)	4 (13.3)
Missing	0 (0.0)	1 (5.9)	1 (3.3)
Pooled Geographic Region per IRT, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Definitive Therapy per IRT, n (%)			
Yes	4 (30.8)	7 (41.2)	11 (36.7)
No	9 (69.2)	10 (58.8)	19 (63.3)

Source: ADSL. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Time from Initial Diagnosis to Study Entry (months)			
n	13	17	30
Mean (SD)	8.30 (16.077)	8.16 (15.719)	8.22 (15.598)
Median	0.95	1.81	1.12
Q1, Q3	0.76, 12.48	0.82, 11.10	0.76, 12.09
Min, Max	0.5, 58.2	0.2, 65.7	0.2, 65.7
Primary Site of Esophageal Cancer, n (%)			
Cervical	0 (0.0)	3 (17.6)	3 (10.0)
Upper thoracic	5 (38.5)	4 (23.5)	9 (30.0)
Middle thoracic	4 (30.8)	5 (29.4)	9 (30.0)
Lower thoracic	4 (30.8)	5 (29.4)	9 (30.0)

Source: ADSL, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Histologic Grade, n (%)			
Gx - Grade cannot be assessed	5 (38.5)	8 (47.1)	13 (43.3)
G1 - Well-differentiated	1 (7.7)	2 (11.8)	3 (10.0)
G2 - Moderately-differentiated	6 (46.2)	6 (35.3)	12 (40.0)
G3 - Poorly differentiated	1 (7.7)	1 (5.9)	2 (6.7)
Histologic Type, n (%)			
Squamous Cell Carcinoma	13 (100.0)	17 (100.0)	30 (100.0)
Other [a]	0 (0.0)	0 (0.0)	0 (0.0)
Disease Stage at Diagnosis [b], n (%)			
Stage I (IA, IB)	1 (7.7)	1 (5.9)	2 (6.7)
Stage II (IIA, IIB)	1 (7.7)	2 (11.8)	3 (10.0)
Stage III (IIIA, IIIB, IIIC)	2 (15.4)	5 (29.4)	7 (23.3)
Stage IV	9 (69.2)	9 (52.9)	18 (60.0)

Source: ADSL, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Disease Status at Study Entry, n (%)			
Metastatic	12 (92.3)	15 (88.2)	27 (90.0)
Locally Advanced	1 (7.7)	2 (11.8)	3 (10.0)
Time from Metastatic Disease to Study Entry (months)			
n	12	15	27
Mean (SD)	1.30 (1.812)	3.51 (10.275)	2.53 (7.713)
Median	0.74	0.72	0.72
Q1, Q3	0.53, 1.33	0.33, 1.38	0.46, 1.35
Min, Max	0.3, 6.9	0.0, 40.6	0.0, 40.6
Number of Metastatic Sites at Study Entry, n (%)			
0	1 (7.7)	2 (11.8)	3 (10.0)
1	9 (69.2)	8 (47.1)	17 (56.7)
2	2 (15.4)	5 (29.4)	7 (23.3)
>2	1 (7.7)	2 (11.8)	3 (10.0)

Source: ADSL, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Locations of Metastases at Study Entry [c], n (%)			
Lymph Nodes	7 (53.8)	6 (35.3)	13 (43.3)
Lung	6 (46.2)	7 (41.2)	13 (43.3)
Liver	2 (15.4)	4 (23.5)	6 (20.0)
Bone	1 (7.7)	1 (5.9)	2 (6.7)
Brain	0 (0.0)	0 (0.0)	0 (0.0)
Peritoneum	0 (0.0)	0 (0.0)	0 (0.0)
Skin	0 (0.0)	0 (0.0)	0 (0.0)
Soft Tissue	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	6 (35.3)	6 (20.0)

Source: ADSL, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Target Lesions Sum of Diameter by Investigator (mm)			
n	13	15	28
Mean (SD)	30.95 (18.422)	54.19 (28.241)	43.40 (26.527)
Median	27.20	54.62	31.00
Q1, Q3	17.00, 43.20	27.00, 75.00	21.35, 62.36
Min, Max	10.4, 67.0	18.8, 109.0	10.4, 109.0
PD-L1 Status, n (%)			
PD-L1 Score < 10%	13 (100.0)	17 (100.0)	30 (100.0)

Source: ADSL, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.

Study Entry date referred to randomization date in this study.

[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.

[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.

[c] A patient was counted only once within each category, but may be counted in multiple categories.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Patients with at Least One Prior Definitive Therapy, n (%) [a]	4 (30.8)	7 (41.2)	11 (36.7)
Definitive Radiotherapy with/without Chemotherapy	0 (0.0)	1 (5.9)	1 (3.3)
Definitive Surgery with/without Adjuvant/Neo-adjuvant Treatment	4 (30.8)	6 (35.3)	10 (33.3)
Time from End of Last Prior Anti-Cancer Therapy to Study Entry [b] (months)			
n	4	8	12
Mean (SD)	22.71 (23.656)	30.69 (58.484)	28.03 (48.422)
Median	13.27	9.82	10.12
Q1, Q3	9.56, 35.86	7.39, 18.07	7.39, 19.81
Min, Max	6.4, 57.9	0.6, 174.4	0.6, 174.4
Prior Anti-Cancer Systemic Therapy, n (%)	2 (15.4)	5 (29.4)	7 (23.3)
Platinum Based Prior Anti-Cancer Systemic Therapy			
Yes	2 (15.4)	5 (29.4)	7 (23.3)
No	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Treatment Setting of Prior Anti-Cancer Systemic Therapies, n (%) [a]			
Neo-adjuvant Setting	2 (15.4)	4 (23.5)	6 (20.0)
Adjuvant Setting	1 (7.7)	0 (0.0)	1 (3.3)
In Combination with Definitive Radiotherapy	0 (0.0)	2 (11.8)	2 (6.7)
Duration of Last Prior Anti-Cancer Systemic Therapy (months)			
n	2	5	7
Mean (SD)	1.81 (1.254)	2.24 (1.291)	2.12 (1.191)
Median	1.81	1.81	1.81
Q1, Q3	0.92, 2.69	1.58, 2.50	0.99, 2.69
Min, Max	0.9, 2.7	1.0, 4.3	0.9, 4.3

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

[a] A patient was counted only once within each category but may be counted in multiple categories.

[b] Study Entry date referred to randomization date in this study.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Radiotherapy, n (%)	1 (7.7)	3 (17.6)	4 (13.3)
Site Irradiated, n (%) [a]			
Brain	0 (0.0)	1 (5.9)	1 (3.3)
Lung - left	0 (0.0)	0 (0.0)	0 (0.0)
Lung - right	0 (0.0)	0 (0.0)	0 (0.0)
Liver	0 (0.0)	0 (0.0)	0 (0.0)
Esophagus	0 (0.0)	1 (5.9)	1 (3.3)
Head and neck	0 (0.0)	0 (0.0)	0 (0.0)
Stomach	0 (0.0)	0 (0.0)	0 (0.0)
Retroperitoneum	1 (7.7)	0 (0.0)	1 (3.3)
Bone	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Anti-Cancer Surgery, n (%)	4 (30.8)	7 (41.2)	11 (36.7)
Surgical Procedure, n (%) [a]			
Esophagectomy - Upper	0 (0.0)	3 (17.6)	3 (10.0)
Esophagectomy - Middle	2 (15.4)	1 (5.9)	3 (10.0)
Esophagectomy - Lower	2 (15.4)	2 (11.8)	4 (13.3)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-pr-crs.sas 21OCT2024 08:35 t-14-1-5-1-pr-crs-pop1-ia.rtf

Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Prior Medication	7 (53.8)	8 (47.1)	15 (50.0)
Amides	2 (15.4)	1 (5.9)	3 (10.0)
Lidocaine	2 (15.4)	1 (5.9)	3 (10.0)
Third-Generation Cephalosporins	2 (15.4)	0 (0.0)	2 (6.7)
Cefditoren Pivoxil	1 (7.7)	0 (0.0)	1 (3.3)
Cefotaxime Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids	1 (7.7)	0 (0.0)	1 (3.3)
Tranexamic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Anesthetics, Local	1 (7.7)	0 (0.0)	1 (3.3)
Dyclonine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Anilides	1 (7.7)	1 (5.9)	2 (6.7)
Paracetamol	1 (7.7)	1 (5.9)	2 (6.7)
Benzodiazepine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Amoxicillin;clavulanic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Contact Laxatives	1 (7.7)	0 (0.0)	1 (3.3)
Sennoside A+b Calcium	1 (7.7)	0 (0.0)	1 (3.3)
Fluoroquinolones	1 (7.7)	0 (0.0)	1 (3.3)
Levofloxacin	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
H2-Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Famotidine	1 (7.7)	0 (0.0)	1 (3.3)
Natural Opium Alkaloids	1 (7.7)	0 (0.0)	1 (3.3)
Hydromorphone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	0 (0.0)	1 (3.3)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	0 (0.0)	1 (3.3)
Aldioxa	1 (7.7)	0 (0.0)	1 (3.3)
Proton Pump Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Esomeprazole Sodium	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	1 (7.7)	2 (11.8)	3 (10.0)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Unspecified Herbal And Traditional Medicine	1 (7.7)	0 (0.0)	1 (3.3)
Ginkgo Biloba Extract	1 (7.7)	0 (0.0)	1 (3.3)
Vitamin B1, Plain	1 (7.7)	0 (0.0)	1 (3.3)
Cetotiamine	1 (7.7)	0 (0.0)	1 (3.3)
Acetic Acid Derivatives And Related Substances	0 (0.0)	2 (11.8)	2 (6.7)
Aceclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Ketorolac Tromethamine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	0 (0.0)	1 (5.9)	1 (3.3)
Candesartan	0 (0.0)	1 (5.9)	1 (3.3)
Dihydropyridine Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)
Electrolyte Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Magnesium Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	0 (0.0)	1 (5.9)	1 (3.3)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefazolin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	0 (0.0)	2 (11.8)	2 (6.7)
Dexamethasone Sodium Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Triamcinolone	0 (0.0)	1 (5.9)	1 (3.3)
Opioid Anesthetics	0 (0.0)	1 (5.9)	1 (3.3)
Fentanyl Citrate	0 (0.0)	1 (5.9)	1 (3.3)
Other Opioids	0 (0.0)	1 (5.9)	1 (3.3)
Tramadol Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccines	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccine Conj 13v (Crm197)	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions For Parenteral Nutrition	0 (0.0)	2 (11.8)	2 (6.7)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Medication	13 (100.0)	17 (100.0)	30 (100.0)
Serotonin (5ht3) Antagonists	12 (92.3)	15 (88.2)	27 (90.0)
Palonosetron Hydrochloride	5 (38.5)	8 (47.1)	13 (43.3)
Granisetron	3 (23.1)	2 (11.8)	5 (16.7)
Ondansetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Tropisetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Netupitant;palonosetron	1 (7.7)	0 (0.0)	1 (3.3)
Ondansetron	1 (7.7)	5 (29.4)	6 (20.0)
Palonosetron	1 (7.7)	0 (0.0)	1 (3.3)
Tropisetron	1 (7.7)	1 (5.9)	2 (6.7)
Granisetron Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	1 (5.9)	2 (6.7)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Sulfonamides, Plain	10 (76.9)	8 (47.1)	18 (60.0)
Furosemide	8 (61.5)	8 (47.1)	16 (53.3)
Torasemide	2 (15.4)	0 (0.0)	2 (6.7)
Indapamide	1 (7.7)	0 (0.0)	1 (3.3)
Other Antiemetics	9 (69.2)	13 (76.5)	22 (73.3)
Aprepitant	7 (53.8)	6 (35.3)	13 (43.3)
Fosaprepitant Meglumine	2 (15.4)	8 (47.1)	10 (33.3)
Prochlorperazine	1 (7.7)	1 (5.9)	2 (6.7)
Promethazine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine Hydrochloride;diprophylline	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)
Prochlorperazine Maleate	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Electrolyte Solutions	8 (61.5)	13 (76.5)	21 (70.0)
Potassium Chloride	6 (46.2)	5 (29.4)	11 (36.7)
Magnesium Sulfate	4 (30.8)	8 (47.1)	12 (40.0)
Calcium Chloride;potassium Chloride;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Electrolyte Solutions [umbrella Term]	0 (0.0)	1 (5.9)	1 (3.3)
Potassium	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Phosphate	0 (0.0)	2 (11.8)	2 (6.7)
Osmotically Acting Laxatives	8 (61.5)	8 (47.1)	16 (53.3)
Magnesium Oxide	6 (46.2)	6 (35.3)	12 (40.0)
Lactulose	2 (15.4)	1 (5.9)	3 (10.0)
Magnesium Hydroxide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-ia.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Proton Pump Inhibitors	8 (61.5)	12 (70.6)	20 (66.7)
Omeprazole	4 (30.8)	1 (5.9)	5 (16.7)
Esomeprazole Sodium	2 (15.4)	0 (0.0)	2 (6.7)
Lansoprazole	2 (15.4)	2 (11.8)	4 (13.3)
Esomeprazole	1 (7.7)	2 (11.8)	3 (10.0)
Esomeprazole Magnesium	1 (7.7)	0 (0.0)	1 (3.3)
Pantoprazole	1 (7.7)	0 (0.0)	1 (3.3)
Dexlansoprazole	0 (0.0)	1 (5.9)	1 (3.3)
Omeprazole Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Pantoprazole Sodium Sesquihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Rabeprazole Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Vonoprazan Fumarate	0 (0.0)	3 (17.6)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	7 (53.8)	12 (70.6)	19 (63.3)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	3 (17.6)	5 (16.7)
Electrolytes Nos;glucose	2 (15.4)	1 (5.9)	3 (10.0)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	0 (0.0)	2 (6.7)
Sodium Chloride	2 (15.4)	7 (41.2)	9 (30.0)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Gluconate Monohydrate;glucose;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate;sodium Chloride;sodium Citrate Dihydrate	1 (7.7)	1 (5.9)	2 (6.7)
Glucose;sodium Chloride	1 (7.7)	2 (11.8)	3 (10.0)
Solutions Affecting The Electrolyte Balance	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Chloride;sodium Lactate	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride;magnesium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;potassium Chloride;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;sodium Chloride;sodium Lactate	0 (0.0)	4 (23.5)	4 (13.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Propulsives	6 (46.2)	6 (35.3)	12 (40.0)
Metoclopramide Dihydrochloride	3 (23.1)	1 (5.9)	4 (13.3)
Domperidone	1 (7.7)	2 (11.8)	3 (10.0)
Metoclopramide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Mosapride Citrate	1 (7.7)	1 (5.9)	2 (6.7)
Alizapride	0 (0.0)	1 (5.9)	1 (3.3)
Antiemetics And Antinauseants	5 (38.5)	10 (58.8)	15 (50.0)
Metoclopramide	4 (30.8)	5 (29.4)	9 (30.0)
Metoclopramide Hydrochloride	1 (7.7)	5 (29.4)	6 (20.0)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Colony Stimulating Factors	5 (38.5)	2 (11.8)	7 (23.3)
Filgrastim	3 (23.1)	1 (5.9)	4 (13.3)
Peg Granulocyte Colony Stimulating Factor	2 (15.4)	0 (0.0)	2 (6.7)
Mecapegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Pegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Granulocyte Colony Stimulating Factor	0 (0.0)	1 (5.9)	1 (3.3)
H2-Receptor Antagonists	5 (38.5)	2 (11.8)	7 (23.3)
Cimetidine	2 (15.4)	0 (0.0)	2 (6.7)
Famotidine	2 (15.4)	1 (5.9)	3 (10.0)
Lafutidine	1 (7.7)	0 (0.0)	1 (3.3)
Ranitidine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Producing Osmotic Diuresis	5 (38.5)	7 (41.2)	12 (40.0)
Mannitol	5 (38.5)	7 (41.2)	12 (40.0)
Anilides	4 (30.8)	9 (52.9)	13 (43.3)
Paracetamol	4 (30.8)	9 (52.9)	13 (43.3)
Blood Substitutes And Perfusion Solutions	4 (30.8)	4 (23.5)	8 (26.7)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	4 (30.8)	4 (23.5)	8 (26.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	4 (30.8)	2 (11.8)	6 (20.0)
Amoxicillin Trihydrate;clavulanate Potassium	1 (7.7)	0 (0.0)	1 (3.3)
Amoxicillin;clavulanic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Ampicillin Sodium;sulbactam Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Contact Laxatives	4 (30.8)	8 (47.1)	12 (40.0)
Sennoside A+b	3 (23.1)	6 (35.3)	9 (30.0)
Bisacodyl	1 (7.7)	3 (17.6)	4 (13.3)
Sennoside A+b Calcium	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Picosulfate	1 (7.7)	4 (23.5)	5 (16.7)
Senna Alexandrina Extract	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Fluoroquinolones	4 (30.8)	2 (11.8)	6 (20.0)
Levofloxacin	3 (23.1)	1 (5.9)	4 (13.3)
Ciprofloxacin	1 (7.7)	0 (0.0)	1 (3.3)
Ofloxacin	0 (0.0)	1 (5.9)	1 (3.3)
Heparin Group	4 (30.8)	3 (17.6)	7 (23.3)
Heparin Calcium	2 (15.4)	0 (0.0)	2 (6.7)
Bemiparin	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin	0 (0.0)	1 (5.9)	1 (3.3)
Heparin Sodium	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Corticosteroids, Potent (Group Iii)	3 (23.1)	1 (5.9)	4 (13.3)
Betamethasone Butyrate Propionate	1 (7.7)	0 (0.0)	1 (3.3)
Halometasone	1 (7.7)	0 (0.0)	1 (3.3)
Mometasone Furoate	1 (7.7)	0 (0.0)	1 (3.3)
Betamethasone Valerate	0 (0.0)	1 (5.9)	1 (3.3)
Difluprednate	0 (0.0)	1 (5.9)	1 (3.3)
Dihydropyridine Derivatives	3 (23.1)	3 (17.6)	6 (20.0)
Cilnidipine	2 (15.4)	0 (0.0)	2 (6.7)
Amlodipine	1 (7.7)	2 (11.8)	3 (10.0)
Lercanidipine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Imidazole And Triazole Derivatives	3 (23.1)	1 (5.9)	4 (13.3)
Clobetasol Propionate;ketoconazole	1 (7.7)	0 (0.0)	1 (3.3)
Clotrimazole	1 (7.7)	0 (0.0)	1 (3.3)
Econazole Nitrate	1 (7.7)	0 (0.0)	1 (3.3)
Lanoconazole	0 (0.0)	1 (5.9)	1 (3.3)
Mucolytics	3 (23.1)	3 (17.6)	6 (20.0)
Acetylcysteine	2 (15.4)	0 (0.0)	2 (6.7)
Ambroxol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Bromhexine Hydrochloride	0 (0.0)	2 (11.8)	2 (6.7)
Carbocisteine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Plain Vitamin Preparations	3 (23.1)	1 (5.9)	4 (13.3)
Pyridoxine Hydrochloride	3 (23.1)	1 (5.9)	4 (13.3)
Potassium	3 (23.1)	2 (11.8)	5 (16.7)
Potassium Chloride	2 (15.4)	0 (0.0)	2 (6.7)
Potassium Aspartate	1 (7.7)	2 (11.8)	3 (10.0)
Potassium Gluconate	0 (0.0)	1 (5.9)	1 (3.3)
Solutions For Parenteral Nutrition	3 (23.1)	6 (35.3)	9 (30.0)
Amino Acids Nos;fats Nos;glucose	2 (15.4)	0 (0.0)	2 (6.7)
Dl-Alpha Tocopheryl Acetate;glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	2 (15.4)	0 (0.0)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetic Acid;alanine;arginine;aspartic Acid;calcium;calcium Chloride;chloride;glucose;glutamate Sodium;glycerol;glycine;glycine Max Seed Oil;histidine;isoleucine;lecithin;leucine;lysine Hydrochloride;magnesium;magnesium Sulfate;methionine;phenylalanine;phosphorus;potassium;potassium Chloride;proline;serine;sodium;sodium Acetate;sodium Glycerophosphate;sodium Hydroxide;threonine;tryptophan, L-;tyrosine;valine	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Glucose	1 (7.7)	2 (11.8)	3 (10.0)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)
Alanine;arginine;aspartic Acid;calcium Chloride;glucose Monohydrate;glutamic Acid;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate;methionine;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	0 (0.0)	2 (11.8)	2 (6.7)
Substituted Alkylamines	3 (23.1)	3 (17.6)	6 (20.0)
Dexchlorpheniramine Maleate	2 (15.4)	2 (11.8)	4 (13.3)
Chlorphenamine	1 (7.7)	0 (0.0)	1 (3.3)
Chlorphenamine Maleate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Unspecified Herbal And Traditional Medicine	3 (23.1)	5 (29.4)	8 (26.7)
Unspecified Herbal And Traditional Medicine	2 (15.4)	0 (0.0)	2 (6.7)
Angelica Sinensis Root;atractylodes Macrocephala, Rhizoma;cremastra Appendiculata Pseudobulb;epimedium Spp.;panax Ginseng Root;solanum Lyratum;sophora Flavescens Root	1 (7.7)	0 (0.0)	1 (3.3)
Animal Unspecified;borneol;cow Bezoar;fungi Nos;indigo;pearl	1 (7.7)	0 (0.0)	1 (3.3)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	0 (0.0)	1 (5.9)	1 (3.3)
Citrus Aurantium Pericarp;creosote;glycyrrhiza Spp. Root With Rhizome;phellodendron Spp. Stem Bark;senegalia Catechu Twig	0 (0.0)	1 (5.9)	1 (3.3)
Coptis Spp.;glycyrrhiza Spp.;panax Ginseng;pinellia Ternata;scutellaria Baicalensis;zingiber Officinale;ziziphus Jujuba	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-ia.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glycine Max Seed Oil	0 (0.0)	1 (5.9)	1 (3.3)
Glycyrrhiza Spp. Root;paeonia Lactiflora Root	0 (0.0)	2 (11.8)	2 (6.7)
Panax Ginseng Root;zanthoxylum Piperitum Pericarp;zingiber Officinale Processed Rhizome	0 (0.0)	1 (5.9)	1 (3.3)
Antiinfectives And Antiseptics For Local Oral Treatment	2 (15.4)	1 (5.9)	3 (10.0)
Chlorhexidine	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Antiinfectives And Antiseptics For Local Oral Treatment	0 (0.0)	1 (5.9)	1 (3.3)
Ascorbic Acid (Vitamin C), Plain	2 (15.4)	1 (5.9)	3 (10.0)
Ascorbic Acid	2 (15.4)	1 (5.9)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Brotizolam	1 (7.7)	2 (11.8)	3 (10.0)
Estazolam	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Midazolam	1 (7.7)	1 (5.9)	2 (6.7)
Alprazolam	0 (0.0)	3 (17.6)	3 (10.0)
Flunitrazepam	0 (0.0)	1 (5.9)	1 (3.3)
Phenazepam	0 (0.0)	1 (5.9)	1 (3.3)
Combinations Of Vitamins	2 (15.4)	0 (0.0)	2 (6.7)
Combinations Of Vitamins	1 (7.7)	0 (0.0)	1 (3.3)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Corticosteroids For Local Oral Treatment	2 (15.4)	2 (11.8)	4 (13.3)
Dexamethasone	2 (15.4)	2 (11.8)	4 (13.3)
Triamcinolone	1 (7.7)	0 (0.0)	1 (3.3)
General Nutrients	2 (15.4)	2 (11.8)	4 (13.3)
General Nutrients	1 (7.7)	2 (11.8)	3 (10.0)
Nutrients Nos	1 (7.7)	0 (0.0)	1 (3.3)
Insulins And Analogues For Injection, Fast-Acting	2 (15.4)	3 (17.6)	5 (16.7)
Insulin	2 (15.4)	1 (5.9)	3 (10.0)
Insulin Human	0 (0.0)	1 (5.9)	1 (3.3)
Insulin Lispro	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Macrolides	2 (15.4)	0 (0.0)	2 (6.7)
Roxithromycin	2 (15.4)	0 (0.0)	2 (6.7)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	2 (15.4)	0 (0.0)	2 (6.7)
Entecavir	2 (15.4)	0 (0.0)	2 (6.7)
Opium Alkaloids And Derivatives	2 (15.4)	1 (5.9)	3 (10.0)
Dextromethorphan	1 (7.7)	0 (0.0)	1 (3.3)
Dextromethorphan Hydrobromide	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antihistamines For Systemic Use	2 (15.4)	1 (5.9)	3 (10.0)
Cyproheptadine	1 (7.7)	0 (0.0)	1 (3.3)
Ebastine	1 (7.7)	0 (0.0)	1 (3.3)
Mebhydrolin	1 (7.7)	0 (0.0)	1 (3.3)
Rupatadine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Other Drugs For Constipation	2 (15.4)	2 (11.8)	4 (13.3)
Glycerol	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	1 (7.7)	2 (11.8)	3 (10.0)
Linaclotide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Immunostimulants	2 (15.4)	1 (5.9)	3 (10.0)
Batilol	1 (7.7)	1 (5.9)	2 (6.7)
Leucogen	1 (7.7)	0 (0.0)	1 (3.3)
Preparations Inhibiting Uric Acid Production	2 (15.4)	3 (17.6)	5 (16.7)
Allopurinol	1 (7.7)	1 (5.9)	2 (6.7)
Febuxostat	1 (7.7)	3 (17.6)	4 (13.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Propionic Acid Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Dexketoprofen	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen	1 (7.7)	1 (5.9)	2 (6.7)
Loxoprofen Sodium	1 (7.7)	3 (17.6)	4 (13.3)
Flurbiprofen Axetil	0 (0.0)	1 (5.9)	1 (3.3)
Loxoprofen Sodium Dihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Zaltoprofen	0 (0.0)	1 (5.9)	1 (3.3)
Acetic Acid Derivatives And Related Substances	1 (7.7)	0 (0.0)	1 (3.3)
Diclofenac Sodium	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	1 (7.7)	0 (0.0)	1 (3.3)
Fluticasone Furoate;vilanterol Trifenatate	1 (7.7)	0 (0.0)	1 (3.3)
Alpha-Adrenoreceptor Antagonists	1 (7.7)	1 (5.9)	2 (6.7)
Silodosin	1 (7.7)	1 (5.9)	2 (6.7)
Amides	1 (7.7)	1 (5.9)	2 (6.7)
Lidocaine	1 (7.7)	0 (0.0)	1 (3.3)
Lidocaine Hydrochloride;prilocaine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Aminoalkyl Ethers	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine	1 (7.7)	0 (0.0)	1 (3.3)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	1 (7.7)	1 (5.9)	2 (6.7)
Cilnidipine;valsartan	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate;telmisartan	0 (0.0)	1 (5.9)	1 (3.3)
Antibiotics	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Rifampicin	1 (7.7)	0 (0.0)	1 (3.3)
Antidotes	1 (7.7)	1 (5.9)	2 (6.7)
Glutathione	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antiinflammatory Preparations, Non-Steroids For Topical Use	1 (7.7)	1 (5.9)	2 (6.7)
Felbinac	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Antipropulsives	1 (7.7)	1 (5.9)	2 (6.7)
Loperamide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Appetite Stimulants	1 (7.7)	0 (0.0)	1 (3.3)
Megestrol	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Related Drugs	1 (7.7)	3 (17.6)	4 (13.3)
Zolpidem	1 (7.7)	0 (0.0)	1 (3.3)
Eszopiclone	0 (0.0)	2 (11.8)	2 (6.7)
Zolpidem Tartrate	0 (0.0)	2 (11.8)	2 (6.7)
Benzomorphan Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Pentazocine	1 (7.7)	0 (0.0)	1 (3.3)
Beta Blocking Agents, Non-Selective	1 (7.7)	0 (0.0)	1 (3.3)
Propranolol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Beta Blocking Agents, Selective	1 (7.7)	2 (11.8)	3 (10.0)
Atenolol	1 (7.7)	0 (0.0)	1 (3.3)
Bisoprolol	1 (7.7)	1 (5.9)	2 (6.7)
Bisoprolol Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Biguanides	1 (7.7)	2 (11.8)	3 (10.0)
Metformin	1 (7.7)	0 (0.0)	1 (3.3)
Metformin Hydrochloride	0 (0.0)	2 (11.8)	2 (6.7)
Calcium, Combinations With Vitamin D And/Or Other Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Carbonate;colecalciferol;magnesium Carbonate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	1 (7.7)	0 (0.0)	1 (3.3)
Almagate	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid;rifampicin	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Various Lipid Modifying Agents	1 (7.7)	0 (0.0)	1 (3.3)
Atorvastatin;ezetimibe	1 (7.7)	0 (0.0)	1 (3.3)
Corticosteroids, Very Potent (Group Iv)	1 (7.7)	1 (5.9)	2 (6.7)
Clobetasol Propionate	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Corticosteroids, Weak (Group I)	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	0 (0.0)	1 (5.9)	1 (3.3)
Coxibs	1 (7.7)	1 (5.9)	2 (6.7)
Etoricoxib	1 (7.7)	0 (0.0)	1 (3.3)
Celecoxib	0 (0.0)	1 (5.9)	1 (3.3)
Diazepines, Oxazepines, Thiazepines And Oxepines	1 (7.7)	4 (23.5)	5 (16.7)
Quetiapine	1 (7.7)	0 (0.0)	1 (3.3)
Olanzapine	0 (0.0)	4 (23.5)	4 (13.3)
Quetiapine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Enemas	1 (7.7)	0 (0.0)	1 (3.3)
Glycerol	1 (7.7)	0 (0.0)	1 (3.3)
Enzymes	1 (7.7)	1 (5.9)	2 (6.7)
Bromelains;cysteine	1 (7.7)	0 (0.0)	1 (3.3)
Pronase;sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	1 (7.7)	4 (23.5)	5 (16.7)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	1 (7.7)	2 (11.8)	3 (10.0)
Carbohydrates Nos;electrolytes Nos;lipids Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Fibrates	1 (7.7)	0 (0.0)	1 (3.3)
Bezafibrate	1 (7.7)	0 (0.0)	1 (3.3)
Heparins Or Heparinoids For Topical Use	1 (7.7)	0 (0.0)	1 (3.3)
Mucopolysaccharide Polysulfuric Acid Ester	1 (7.7)	0 (0.0)	1 (3.3)
Hmg Coa Reductase Inhibitors	1 (7.7)	3 (17.6)	4 (13.3)
Pravastatin	1 (7.7)	1 (5.9)	2 (6.7)
Simvastatin	1 (7.7)	1 (5.9)	2 (6.7)
Rosuvastatin	0 (0.0)	1 (5.9)	1 (3.3)
Hydrazides	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	1 (7.7)	1 (5.9)	2 (6.7)
Insulin Human;insulin Human Injection, Isophane	1 (7.7)	0 (0.0)	1 (3.3)
Insulin Aspart;insulin Aspart Protamine (Crystalline)	0 (0.0)	1 (5.9)	1 (3.3)
Leukotriene Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Montelukast	1 (7.7)	0 (0.0)	1 (3.3)
Medical Gases	1 (7.7)	0 (0.0)	1 (3.3)
Oxygen	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Natural Opium Alkaloids	1 (7.7)	6 (35.3)	7 (23.3)
Codeine	1 (7.7)	0 (0.0)	1 (3.3)
Codeine Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Hydromorphone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Naloxone Hydrochloride;oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Agents For Local Oral Treatment	1 (7.7)	6 (35.3)	7 (23.3)
Sodium Gualenate Hydrate	1 (7.7)	3 (17.6)	4 (13.3)
Benzydamine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Diclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Glycerol	0 (0.0)	1 (5.9)	1 (3.3)
Lidocaine	0 (0.0)	2 (11.8)	2 (6.7)
Other Analgesics And Antipyretics	1 (7.7)	1 (5.9)	2 (6.7)
Pregabalin	1 (7.7)	1 (5.9)	2 (6.7)
Other Antibiotics For Topical Use	1 (7.7)	1 (5.9)	2 (6.7)
Mupirocin	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antidepressants	1 (7.7)	2 (11.8)	3 (10.0)
Mianserin	1 (7.7)	0 (0.0)	1 (3.3)
Trazodone	0 (0.0)	1 (5.9)	1 (3.3)
Trazodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Other Antidiarrheals	1 (7.7)	0 (0.0)	1 (3.3)
Racecadotril	1 (7.7)	0 (0.0)	1 (3.3)
Other Dermatologicals	1 (7.7)	0 (0.0)	1 (3.3)
Camphor;methyl Salicylate	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs Affecting Bone Structure And Mineralization	1 (7.7)	0 (0.0)	1 (3.3)
Denosumab	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	1 (5.9)	2 (6.7)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Simeticone	0 (0.0)	1 (5.9)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	1 (5.9)	2 (6.7)
Sucralfate	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Alginate	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)
Other Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Ethambutol	1 (7.7)	0 (0.0)	1 (3.3)
Pyrazinamide	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Hypnotics And Sedatives	1 (7.7)	2 (11.8)	3 (10.0)
Doxepin Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Suvorexant	0 (0.0)	2 (11.8)	2 (6.7)
Other Intestinal Adsorbents	1 (7.7)	1 (5.9)	2 (6.7)
Montmorillonite	1 (7.7)	0 (0.0)	1 (3.3)
Gelatin Tannate	0 (0.0)	1 (5.9)	1 (3.3)
Other Nervous System Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Mecobalamin	1 (7.7)	0 (0.0)	1 (3.3)
Other Throat Preparations	1 (7.7)	0 (0.0)	1 (3.3)
Benzydamine	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Viral Vaccines	1 (7.7)	2 (11.8)	3 (10.0)
Covid-19 Vaccine Mrna (Mrna 1273)	1 (7.7)	0 (0.0)	1 (3.3)
Tozinameran	0 (0.0)	2 (11.8)	2 (6.7)
Penicillins With Extended Spectrum	1 (7.7)	1 (5.9)	2 (6.7)
Amoxicillin	1 (7.7)	0 (0.0)	1 (3.3)
Amoxicillin Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Phenothiazines With Aliphatic Side-Chain	1 (7.7)	3 (17.6)	4 (13.3)
Chlorpromazine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Chlorpromazine	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Piperazine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Levocetirizine	1 (7.7)	0 (0.0)	1 (3.3)
Platelet Aggregation Inhibitors Excl. Heparin	1 (7.7)	2 (11.8)	3 (10.0)
Acetylsalicylate Lysine	1 (7.7)	1 (5.9)	2 (6.7)
Acetylsalicylic Acid	0 (0.0)	1 (5.9)	1 (3.3)
Pyrazolones	1 (7.7)	0 (0.0)	1 (3.3)
Metamizole	1 (7.7)	0 (0.0)	1 (3.3)
Second-Generation Cephalosporins	1 (7.7)	1 (5.9)	2 (6.7)
Cefaclor	1 (7.7)	0 (0.0)	1 (3.3)
Cefuroxime	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Selective Beta-2-Adrenoreceptor Agonists	1 (7.7)	1 (5.9)	2 (6.7)
Bambuterol	1 (7.7)	0 (0.0)	1 (3.3)
Tulobuterol	0 (0.0)	1 (5.9)	1 (3.3)
Selective Serotonin Reuptake Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Sertraline	1 (7.7)	0 (0.0)	1 (3.3)
Third-Generation Cephalosporins	1 (7.7)	2 (11.8)	3 (10.0)
Ceftriaxone Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Cefcapene Pivoxil Hydrochloride Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Cefoperazone	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Tonics	1 (7.7)	0 (0.0)	1 (3.3)
Inosine;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Vitamins	1 (7.7)	1 (5.9)	2 (6.7)
Ascorbic Acid;biotin;cocarboxylase Tetrahydrate;colecalciferol;cyanocobalamin;dexpanthenol;dl-Alpha Tocopherol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)
Ace Inhibitors, Plain	0 (0.0)	2 (11.8)	2 (6.7)
Perindopril	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids	0 (0.0)	1 (5.9)	1 (3.3)
Fenoterol Hydrobromide;ipratropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)
Aldose Reductase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Epalrestat	0 (0.0)	1 (5.9)	1 (3.3)
Aldosterone Antagonists	0 (0.0)	2 (11.8)	2 (6.7)
Spironolactone	0 (0.0)	2 (11.8)	2 (6.7)
Alpha Glucosidase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Voglibose	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Amino Acids And Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Ademetionine	0 (0.0)	1 (5.9)	1 (3.3)
Antidiarrheal Microorganisms	0 (0.0)	3 (17.6)	3 (10.0)
Antidiarrheal Microorganisms	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Subtilis;lactomin	0 (0.0)	1 (5.9)	1 (3.3)
Antiseptics	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate;sodium Gualenate Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	0 (0.0)	1 (5.9)	1 (3.3)
Cimetropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzamides	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)
Beta Blocking Agents	0 (0.0)	1 (5.9)	1 (3.3)
Timolol	0 (0.0)	1 (5.9)	1 (3.3)
Bioflavonoids	0 (0.0)	1 (5.9)	1 (3.3)
Diosmin;hesperidin	0 (0.0)	1 (5.9)	1 (3.3)
Bisphosphonates	0 (0.0)	1 (5.9)	1 (3.3)
Zoledronic Acid	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Butyrophenone Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Haloperidol	0 (0.0)	2 (11.8)	2 (6.7)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Carbamide Products	0 (0.0)	1 (5.9)	1 (3.3)
Urea	0 (0.0)	1 (5.9)	1 (3.3)
Carbapenems	0 (0.0)	2 (11.8)	2 (6.7)
Meropenem	0 (0.0)	1 (5.9)	1 (3.3)
Meropenem Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Oral Blood Glucose Lowering Drugs	0 (0.0)	1 (5.9)	1 (3.3)
Metformin Hydrochloride;sitagliptin Phosphate Monohydrate	0 (0.0)	1 (5.9)	1 (3.3)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	0 (0.0)	4 (23.5)	4 (13.3)
Linagliptin	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate Monohydrate	0 (0.0)	2 (11.8)	2 (6.7)
Diphenylmethane Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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Percentages were based on N.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Direct Factor Xa Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Apixaban	0 (0.0)	1 (5.9)	1 (3.3)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefradine	0 (0.0)	1 (5.9)	1 (3.3)
Iron Trivalent, Oral Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Ferric Pyrophosphate	0 (0.0)	1 (5.9)	1 (3.3)
Iron, Parenteral Preparations	0 (0.0)	2 (11.8)	2 (6.7)
Saccharated Iron Oxide	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Liver Therapy	0 (0.0)	2 (11.8)	2 (6.7)
Cysteine Hydrochloride;glycine;glycyrrhizic Acid, Ammonium Salt	0 (0.0)	1 (5.9)	1 (3.3)
Ornithine Aspartate	0 (0.0)	1 (5.9)	1 (3.3)
Polyene Phosphatidylcholine	0 (0.0)	1 (5.9)	1 (3.3)
Melatonin Receptor Agonists	0 (0.0)	1 (5.9)	1 (3.3)
Ramelteon	0 (0.0)	1 (5.9)	1 (3.3)
Other Aminoglycosides	0 (0.0)	1 (5.9)	1 (3.3)
Amikacin	0 (0.0)	1 (5.9)	1 (3.3)
Other Antianemic Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Darbepoetin Alfa	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antibacterials	0 (0.0)	1 (5.9)	1 (3.3)
Fosfomycin	0 (0.0)	1 (5.9)	1 (3.3)
Other Antiepileptics	0 (0.0)	1 (5.9)	1 (3.3)
Lacosamide	0 (0.0)	1 (5.9)	1 (3.3)
Levetiracetam	0 (0.0)	1 (5.9)	1 (3.3)
Other Antipruritics	0 (0.0)	1 (5.9)	1 (3.3)
Crotamiton	0 (0.0)	1 (5.9)	1 (3.3)
Other Blood Products	0 (0.0)	1 (5.9)	1 (3.3)
Blood, Whole	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Centrally Acting Agents	0 (0.0)	1 (5.9)	1 (3.3)
Baclofen	0 (0.0)	1 (5.9)	1 (3.3)
Other Emollients And Protectives	0 (0.0)	2 (11.8)	2 (6.7)
Mucopolysaccharide Polysulfuric Acid Ester	0 (0.0)	2 (11.8)	2 (6.7)
Other Irrigating Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Mannitol;sorbitol	0 (0.0)	1 (5.9)	1 (3.3)
Peripheral Opioid Receptor Antagonists	0 (0.0)	1 (5.9)	1 (3.3)
Naldemedine Tosilate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Phenylpiperidine Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Fentanyl Citrate	0 (0.0)	2 (11.8)	2 (6.7)
Preparations Increasing Uric Acid Excretion	0 (0.0)	1 (5.9)	1 (3.3)
Benzbromarone	0 (0.0)	1 (5.9)	1 (3.3)
Preparations With No Effect On Uric Acid Metabolism	0 (0.0)	1 (5.9)	1 (3.3)
Colchicine	0 (0.0)	1 (5.9)	1 (3.3)
Proteinase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Camostat Mesilate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic (Monohydrate)	0 (0.0)	1 (5.9)	1 (3.3)
Soft Paraffin And Fat Products	0 (0.0)	1 (5.9)	1 (3.3)
White Soft Paraffin	0 (0.0)	1 (5.9)	1 (3.3)
Stomatological Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)
Sulfonylureas	0 (0.0)	1 (5.9)	1 (3.3)
Gliclazide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Triazole Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Fluconazole	0 (0.0)	1 (5.9)	1 (3.3)
Various Alimentary Tract And Metabolism Products	0 (0.0)	2 (11.8)	2 (6.7)
Borneol;cow Bezoar;musk;pearl;potassium Nitrate;realgar;sodium Borate Decahydrate;zingiber Officinale Rhizome	0 (0.0)	1 (5.9)	1 (3.3)
Zinc Acetate	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Disulfide	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Vitamin B12 (Cyanocobalamin And Analogues)	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin B12 Nos	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D And Analogues	0 (0.0)	2 (11.8)	2 (6.7)
Colecalciferol	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D Nos	0 (0.0)	1 (5.9)	1 (3.3)
Xanthines	0 (0.0)	1 (5.9)	1 (3.3)
Theophylline	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Systemically Administered Corticosteroids/Immunosuppressive Drug During the Study	10 (76.9)	14 (82.4)	24 (80.0)
Patients with at Least One Concomitant Systemically Administered Corticosteroids Drugs	10 (76.9)	14 (82.4)	24 (80.0)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm1.sas 21OCT2024 08:30 t-14-1-7-2-cm1-cor-pop1-ia.rtf

Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	1 (5.9)	2 (6.7)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Immunosuppressive Drugs	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Overall Survival [a]			
n	13	17	30
Mean (SD)	19.85 (7.789)	12.99 (8.743)	15.96 (8.901)
Median	19.61	9.76	18.48
Q1, Q3	18.17, 24.80	6.97, 19.12	7.98, 23.82
Min, Max	1.8, 30.1	2.2, 30.3	1.8, 30.3
Progression-Free Survival [b]			
n	13	17	30
Mean (SD)	10.70 (10.082)	7.30 (8.033)	8.77 (8.977)
Median	5.68	4.44	5.52
Q1, Q3	2.83, 17.28	2.07, 8.54	2.76, 9.95
Min, Max	1.8, 29.7	1.2, 29.9	1.2, 29.9

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Investigator Tumor Assessment [c]			
n	13	17	30
Mean (SD)	10.75 (10.049)	7.44 (7.962)	8.88 (8.918)
Median	5.68	4.44	5.60
Q1, Q3	4.04, 17.28	2.66, 8.54	2.76, 9.95
Min, Max	1.3, 29.7	1.2, 29.9	1.2, 29.9
EORTC-QLQ-C30 [d]			
n	13	17	30
Mean (SD)	8.56 (9.092)	7.58 (8.173)	8.01 (8.444)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 27.4	1.0, 29.9	0.0, 29.9

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
EORTC-QLQ-OES18 [d]			
n	13	17	30
Mean (SD)	8.56 (9.092)	7.58 (8.173)	8.01 (8.444)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 27.4	1.0, 29.9	0.0, 29.9
EQ-5D VAS [d]			
n	13	17	30
Mean (SD)	8.76 (9.539)	7.58 (8.173)	8.09 (8.652)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 29.9	1.0, 29.9	0.0, 29.9

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.2:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Safety for TEAEs [a]			
n	13	17	30
Mean (SD)	10.94 (10.638)	7.74 (8.205)	9.13 (9.304)
Median	5.98	4.63	5.52
Q1, Q3	2.99, 19.22	2.17, 8.80	2.83, 10.28
Min, Max	1.2, 30.1	1.2, 30.3	1.2, 30.3
Safety for imAEs [b]			
n	13	17	30
Mean (SD)	12.39 (9.938)	9.19 (7.927)	10.58 (8.840)
Median	7.95	6.60	7.31
Q1, Q3	5.22, 19.22	3.94, 11.53	4.17, 12.71
Min, Max	1.8, 30.1	2.1, 30.3	1.8, 30.3

Source: ADSL, ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event; imAE, immune-mediated adverse event.

[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.

[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Number of Patients		
Death, n (%)	4 (30.8)	10 (58.8)
Censored, n (%)	9 (69.2)	7 (41.2)
Ongoing Without Events	9 (69.2)	5 (29.4)
Lost to Follow-up	0 (0.0)	1 (5.9)
Withdrawal by Subject	0 (0.0)	1 (5.9)
Two-sided Stratified Log-rank Test p-value [a]	0.2518	
Stratified Hazard Ratio (95% CI) [b]	0.435 (0.102, 1.856)	
Unstratified Hazard Ratio (95% CI) [c]	0.350 (0.109, 1.127)	

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Overall Survival (months)		
Median (95% CI)	NR (16.4, NE)	11.8 (7.0, NE)
Q1 (95% CI)	19.6 (1.8, NE)	8.0 (2.2, 11.8)
Q3 (95% CI)	NR (NE, NE)	23.8 (11.8, NE)

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	92.3 (56.6, 98.9)	88.2 (60.6, 96.9)
6 Months (95% CI)	92.3 (56.6, 98.9)	82.4 (54.7, 93.9)
9 Months (95% CI)	84.6 (51.2, 95.9)	69.1 (40.7, 85.9)
12 Months (95% CI)	84.6 (51.2, 95.9)	48.4 (22.5, 70.2)
18 Months (95% CI)	76.9 (44.2, 91.9)	48.4 (22.5, 70.2)
24 Months (95% CI)	65.9 (31.5, 86.0)	24.2 (4.5, 52.3)
30 Months (95% CI)	65.9 (31.5, 86.0)	24.2 (4.5, 52.3)
36 Months (95% CI)	NR (NE, NE)	NR (NE, NE)
42 Months (95% CI)	NR (NE, NE)	NR (NE, NE)

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
48 Months (95% CI)	NR (NE, NE)	NR (NE, NE)
Follow-up Time (months)		
Median (95% CI)	24.0 (18.2, 28.6)	19.1 (17.9, NE)

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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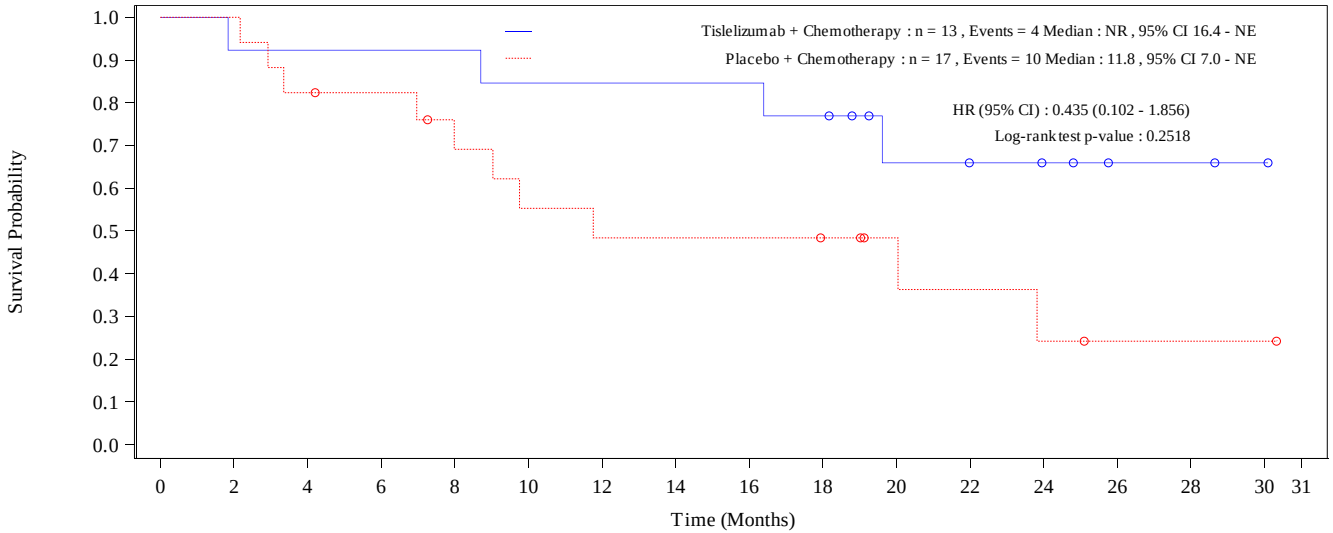
Figure 14.2.1.1:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Tislelizumab +Chemotherapy	13	13	12	12	12	12	12	12	12	11	11	11	11	11	11	11	11	10	10	8	6	6	5	5	4	3	2	2	2	1	1	0
Placebo +Chemotherapy	17	17	17	15	14	13	13	12	10	10	8	8	7	7	7	7	7	7	6	6	4	3	3	3	2	2	1	1	1	1	1	0

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE, not estimable; NR, not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy. (yes vs no) per IRT.
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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	6 (66.7)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	NR (1.8, NE)	11	6 (54.5)	20.0 (2.9, NE)	0.607 (0.169, 2.181)	0.4394
Female	4	0 (0.0)	NR (NE, NE)	6	4 (66.7)	9.8 (7.0, NE)	0.000 (0.000, NE)	0.0327
Interaction								0.9934

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	19.6 (8.7, NE)	10	7 (70.0)	9.8 (2.9, NE)	0.343 (0.086, 1.362)	0.1126
1	6	1 (16.7)	NR (1.8, NE)	7	3 (42.9)	20.0 (2.2, NE)	0.362 (0.037, 3.526)	0.3621
Interaction								0.7864
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	5 (71.4)	--	--	--
No	9	2 (22.2)	--	10	5 (50.0)	--	--	--
Interaction								--

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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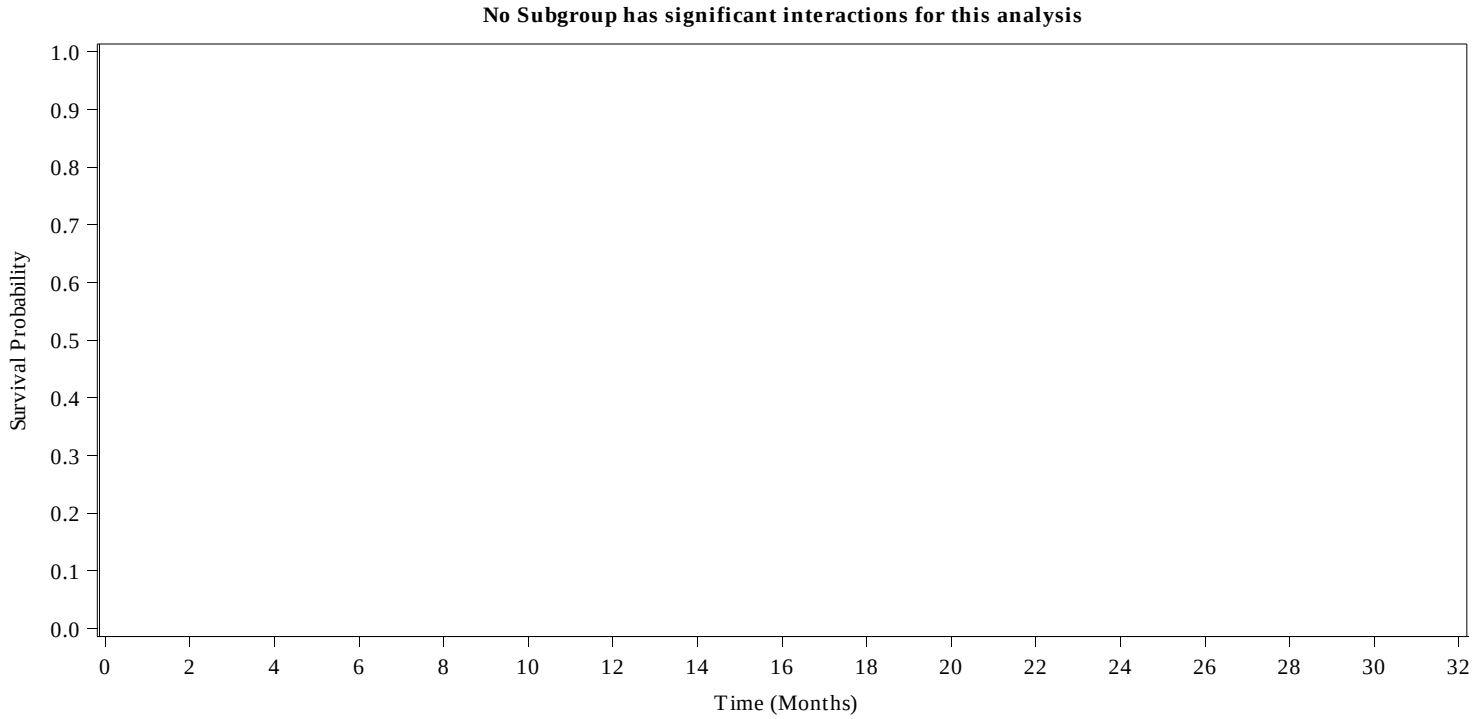
Figure 14.2.1.1.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression-Free Survival		
Events, n (%)	8 (61.5)	14 (82.4)
Progressive Disease	7 (53.8)	14 (82.4)
Death	1 (7.7)	0 (0.0)
Censored, n (%)	5 (38.5)	3 (17.6)
New Anti-Cancer Therapy	1 (7.7)	1 (5.9)
No PD/Death [a]	4 (30.8)	2 (11.8)
Ongoing Without Events	4 (30.8)	2 (11.8)
Two-sided Stratified Log-rank Test p-value [b]	0.2759	
Stratified Hazard Ratio (95% CI) [c]	0.580 (0.216, 1.557)	
Unstratified Hazard Ratio (95% CI) [d]	0.574 (0.240, 1.372)	

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression Free Survival (months)		
Median (95% CI)	6.9 (2.8, NE)	4.4 (1.3, 8.5)
Q1 (95% CI)	5.6 (1.8, 5.7)	2.1 (1.2, 4.1)
Q3 (95% CI)	NR (5.7, NE)	8.5 (4.4, NE)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	76.9 (44.2, 91.9)	58.8 (32.5, 77.8)
6 Months (95% CI)	51.3 (21.9, 74.6)	35.3 (14.5, 57.0)
9 Months (95% CI)	34.2 (10.7, 59.8)	23.5 (7.3, 44.9)
12 Months (95% CI)	34.2 (10.7, 59.8)	17.6 (4.3, 38.3)

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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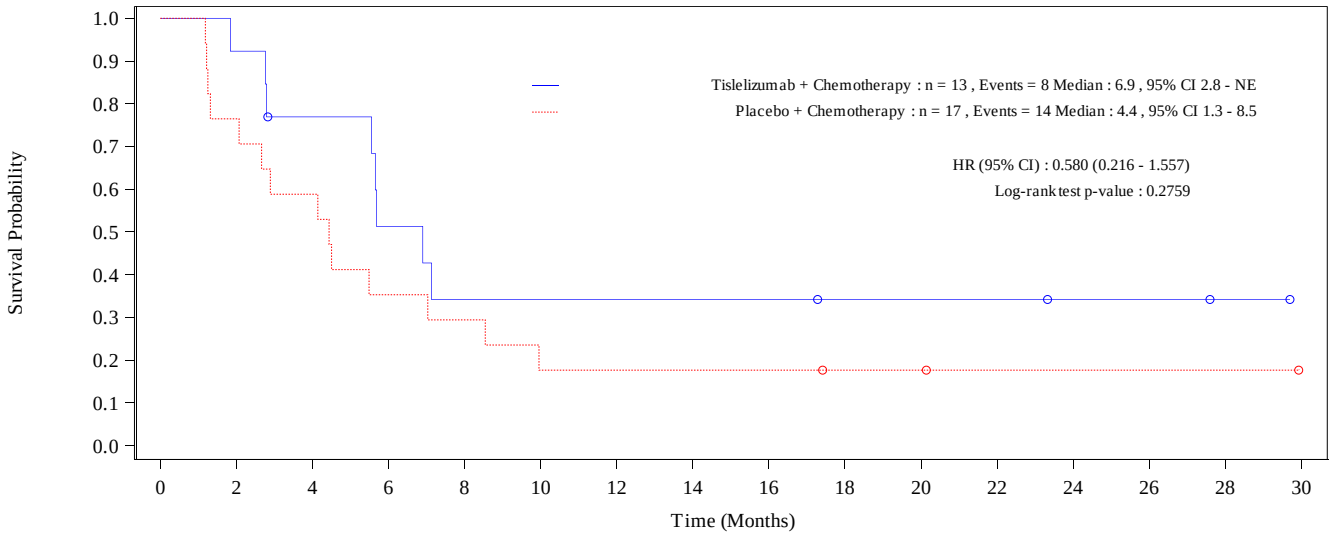
Figure 14.2.4.1:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Tislelizumab +Chemotherapy	13	13	12	9	9	9	6	5	4	4	4	4	4	4	4	4	4	4	3	3	3	3	3	3	2	2	2	2	1	1	0
Placebo +Chemotherapy	17	17	13	10	10	7	6	6	5	4	3	3	3	3	3	3	3	3	2	2	2	1	1	1	1	1	1	1	1	1	0

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE, not estimable.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	5 (55.6)	5.7 (2.8, NE)	8	6 (75.0)	3.5 (1.2, NE)	0.525 (0.159, 1.730)	0.2813
Age >= 65	4	3 (75.0)	6.9 (1.8, NE)	9	8 (88.9)	4.5 (1.2, 10.0)	1.095 (0.272, 4.409)	0.8987
Interaction								0.5174
Sex								
Male	9	7 (77.8)	5.7 (1.8, 7.1)	11	9 (81.8)	4.1 (1.2, 10.0)	1.032 (0.376, 2.836)	0.9514
Female	4	1 (25.0)	NR (2.8, NE)	6	5 (83.3)	4.5 (1.2, NE)	0.213 (0.025, 1.842)	0.1226
Interaction								0.1343

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	5.7 (2.8, NE)	10	9 (90.0)	4.5 (1.3, 7.0)	0.988 (0.338, 2.886)	0.9824
1	6	2 (33.3)	NR (1.8, NE)	7	5 (71.4)	2.9 (1.2, NE)	0.322 (0.062, 1.671)	0.1555
Interaction								0.2158

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	5.7 (2.8, NE)	7	5 (71.4)	4.5 (1.2, NE)	0.547 (0.105, 2.850)	0.4677
No	9	6 (66.7)	6.9 (1.8, NE)	10	9 (90.0)	4.3 (1.2, 8.5)	0.562 (0.199, 1.585)	0.2695
Interaction								0.9597

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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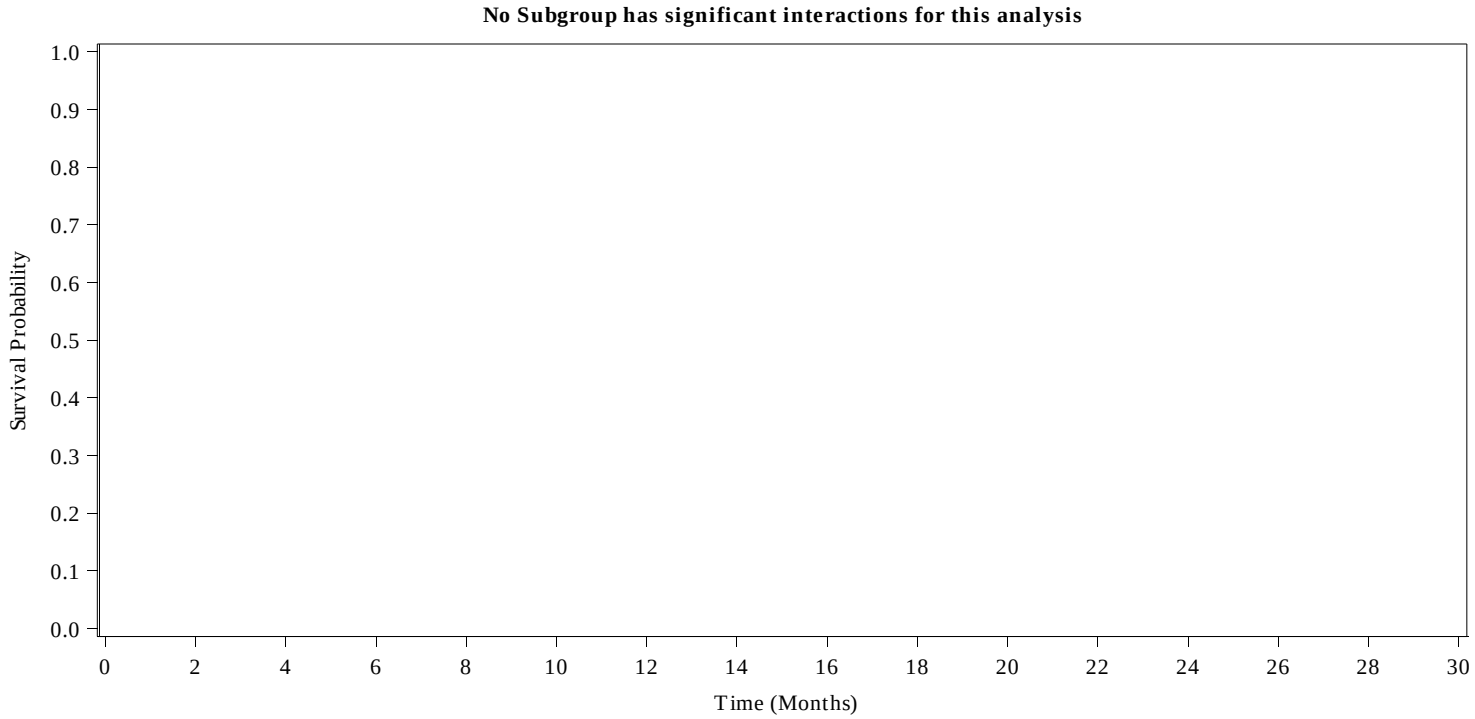
Figure 14.2.4.1.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.2.4.1:
Objective Response
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	11	8				
%	84.6	47.1	5.133 (0.675, 39.019)	1.477 (0.952, 2.292)	27.000 (-5.071, 59.071)	0.1117
Best Overall Response (BOR), n (%)						
Complete Response (CR)	2 (15.4)	1 (5.9)				
Partial Response (PR)	9 (69.2)	7 (41.2)				
Stable Disease (SD) [e]	2 (15.4)	5 (29.4)				
Progressive Disease (PD)	0 (0.0)	4 (23.5)				
Not Evaluable (NE) [c]	0 (0.0)	0 (0.0)				
Not Assessable [d]	0 (0.0)	0 (0.0)				
Disease Control Rate (DCR), n	13	13				
%	100.0	76.5	NE (NE, NE)	1.292 (0.981, 1.702)	22.600 (0.459, 44.741)	0.0975

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE, not estimable.

Percentages were based on N. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[c] Not evaluable is based on RECIST v1.1.

[d] Patients with no post-baseline tumor assessment by the data cutoff, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.

[e] SD includes SD and non-CR/non-PD.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Age								
Age < 65	9	7 (77.8)	8	3 (37.5)	5.833 (0.696, 48.873)	2.074 (0.794, 5.419)	40.278 (-2.887, 83.442)	0.1023
Age >= 65	4	4 (100.0)	9	5 (55.6)	NE (NE, NE)	1.800 (1.003, 3.229)	44.444 (11.981, 76.908)	0.1237
Interaction								0.4682
Sex								
Male	9	8 (88.9)	11	5 (45.5)	9.600 (0.876, 105.166)	1.956 (0.983, 3.888)	43.434 (7.554, 79.315)	0.0483
Female	4	3 (75.0)	6	3 (50.0)	3.000 (0.188, 47.963)	1.500 (0.563, 3.997)	25.000 (-33.321, 83.321)	0.4533
Interaction								0.5300

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
ECOG Performance Score								
0	7	5 (71.4)	10	5 (50.0)	2.500 (0.320, 19.529)	1.429 (0.657, 3.107)	21.429 (-24.182, 67.039)	0.3914
1	6	6 (100.0)	7	3 (42.9)	NE (NE, NE)	2.333 (0.992, 5.489)	57.143 (20.483, 93.803)	0.0325
Interaction								0.1711
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	7	2 (28.6)	7.500 (0.458, 122.696)	2.625 (0.715, 9.640)	46.429 (-7.614, 100.000)	0.1561
No	9	8 (88.9)	10	6 (60.0)	5.333 (0.468, 60.797)	1.481 (0.849, 2.584)	28.889 (-7.765, 65.543)	0.1646
Interaction								0.8566

Source: ADSL, ADTTE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 28		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 30		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	50.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 40		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 42		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	0	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
End of Treatment		
Patients in study at visit, n	9	15
Patients complete questionnaire, n	9	14
Completion rate (%) [a]	69.2	82.4
Adjusted completion rate (%) [b]	100.0	93.3

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	11
Completion rate (%) [a]	84.6	64.7
Adjusted completion rate (%) [b]	100.0	91.7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 28		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 30		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	50.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 40		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 42		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	0	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
End of Treatment		
Patients in study at visit, n	9	15
Patients complete questionnaire, n	9	14
Completion rate (%) [a]	69.2	82.4
Adjusted completion rate (%) [b]	100.0	93.3

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	8	9
Completion rate (%) [a]	61.5	52.9
Adjusted completion rate (%) [b]	88.9	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 28		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 30		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 40		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 42		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	0	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
End of Treatment		
Patients in study at visit, n	9	15
Patients complete questionnaire, n	9	14
Completion rate (%) [a]	69.2	82.4
Adjusted completion rate (%) [b]	100.0	93.3

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	63.2 (29.83)		57.8 (25.08)	
	Median	83.3		50.0	
	Q1, Q3	37.5, 83.3		50.0, 75.0	
	Min, Max	0, 83		8, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	74.2 (16.87)	10.8 (26.95)	62.2 (20.14)	5.6 (20.33)
	Median	83.3	4.2	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 8.3	50.0, 83.3	-8.3, 25.0
	Min, Max	33, 92	-17, 67	25, 83	-42, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	75.8 (12.08)	12.5 (28.40)	62.5 (26.94)	5.6 (20.21)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 33.3	58.3, 75.0	0.0, 16.7
	Min, Max	58, 92	-25, 67	8, 100	-33, 50

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	77.8 (13.82)	16.7 (23.57)	60.4 (27.55)	3.5 (26.93)
	Median	83.3	8.3	75.0	4.2
	Q1, Q3	66.7, 83.3	0.0, 41.7	41.7, 79.2	-16.7, 20.8
	Min, Max	50, 92	-8, 50	8, 83	-42, 42
Cycle 5	n	8	8	11	11
	Mean (SD)	78.1 (17.78)	12.5 (19.42)	64.4 (26.38)	3.0 (28.69)
	Median	83.3	4.2	66.7	16.7
	Q1, Q3	70.8, 87.5	0.0, 29.2	41.7, 83.3	-25.0, 16.7
	Min, Max	42, 100	-8, 42	17, 100	-42, 42
Cycle 6	n	7	7	9	9
	Mean (SD)	81.0 (11.50)	6.0 (15.75)	71.3 (24.69)	7.4 (28.09)
	Median	83.3	0.0	83.3	0.0
	Q1, Q3	66.7, 83.3	0.0, 16.7	66.7, 83.3	-8.3, 33.3
	Min, Max	67, 100	-17, 33	17, 100	-33, 50

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	81.0 (15.00)	17.9 (22.79)	85.7 (11.50)	17.9 (26.97)
	Median	83.3	8.3	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 100.0	0.0, 41.7
	Min, Max	50, 100	0, 50	67, 100	-8, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (27.22)	16.7 (23.57)	75.0 (29.34)	6.9 (36.29)
	Median	66.7	25.0	83.3	4.2
	Q1, Q3	50.0, 83.3	0.0, 33.3	83.3, 83.3	-8.3, 41.7
	Min, Max	33, 100	-17, 33	17, 100	-50, 50
Cycle 12	n	3	3	5	5
	Mean (SD)	75.0 (14.43)	36.1 (42.76)	70.0 (21.73)	8.3 (31.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	58.3, 83.3	0.0, 83.3	66.7, 83.3	-8.3, 25.0
	Min, Max	58, 83	0, 83	33, 83	-33, 50

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	80.6 (12.73)	41.7 (30.05)	75.0 (8.33)	16.7 (22.05)
	Median	83.3	50.0	75.0	8.3
	Q1, Q3	66.7, 91.7	8.3, 66.7	66.7, 83.3	0.0, 41.7
	Min, Max	67, 92	8, 67	67, 83	0, 42
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	38.9 (25.46)	66.7 (23.57)	-12.5 (5.89)
	Median	66.7	33.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	16.7, 66.7	50.0, 83.3	-16.7, -8.3
	Min, Max	67, 100	17, 67	50, 83	-17, -8
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (34.69)	16.7 (16.67)	72.2 (19.25)	-5.6 (12.73)
	Median	66.7	16.7	83.3	-8.3
	Q1, Q3	16.7, 83.3	0.0, 33.3	50.0, 83.3	-16.7, 8.3
	Min, Max	17, 83	0, 33	50, 83	-17, 8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	72.2 (19.25)	33.3 (28.87)	80.6 (4.81)	2.8 (9.62)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 83.3	0.0, 50.0	75.0, 83.3	-8.3, 8.3
	Min, Max	50, 83	0, 50	75, 83	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (25.46)	38.9 (19.25)	77.8 (9.62)	0.0 (22.05)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 100.0	16.7, 50.0	66.7, 83.3	-25.0, 16.7
	Min, Max	50, 100	17, 50	67, 83	-25, 17
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	83.3 (0.00)	5.6 (12.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 83.3	-8.3, 16.7
	Min, Max	83, 83	0, 50	83, 83	-8, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	83.3 (0.00)	0.0 (11.79)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 83.3	-8.3, 8.3
	Min, Max	83, 83	0, 50	83, 83	-8, 8
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	25.0 (11.79)	83.3 (NE)	-8.3 (NE)
	Median	83.3	25.0	83.3	-8.3
	Q1, Q3	66.7, 100.0	16.7, 33.3	83.3, 83.3	-8.3, -8.3
	Min, Max	67, 100	17, 33	83, 83	-8, -8
Cycle 30	n	2	2	1	1
	Mean (SD)	66.7 (23.57)	50.0 (0.00)	83.3 (NE)	-8.3 (NE)
	Median	66.7	50.0	83.3	-8.3
	Q1, Q3	50.0, 83.3	50.0, 50.0	83.3, 83.3	-8.3, -8.3
	Min, Max	50, 83	50, 50	83, 83	-8, -8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	33.3 (0.00)	83.3 (NE)	-8.3 (NE)
	Median	50.0	33.3	83.3	-8.3
	Q1, Q3	33.3, 66.7	33.3, 33.3	83.3, 83.3	-8.3, -8.3
	Min, Max	33, 67	33, 33	83, 83	-8, -8
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	33.3 (0.00)	75.0 (NE)	-16.7 (NE)
	Median	50.0	33.3	75.0	-16.7
	Q1, Q3	33.3, 66.7	33.3, 33.3	75.0, 75.0	-16.7, -16.7
	Min, Max	33, 67	33, 33	75, 75	-17, -17
Cycle 36	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-8.3 (NE)
	Median			83.3	-8.3
	Q1, Q3			83.3, 83.3	-8.3, -8.3
	Min, Max			83, 83	-8, -8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			91.7 (NE)	0.0 (NE)
	Median			91.7	0.0
	Q1, Q3			91.7, 91.7	0.0, 0.0
	Min, Max			92, 92	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
End of Treatment	n	9	9	14	14
	Mean (SD)	72.2 (9.32)	1.9 (26.93)	58.3 (26.95)	3.0 (23.25)
	Median	66.7	-8.3	66.7	0.0
	Q1, Q3	66.7, 83.3	-16.7, 0.0	33.3, 75.0	-8.3, 8.3
	Min, Max	58, 83	-25, 58	0, 100	-50, 42

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	56.9 (22.14)	-6.3 (13.35)	44.1 (23.89)	-13.7 (21.84)
	Median	66.7	-8.3	50.0	-8.3
	Q1, Q3	45.8, 66.7	-16.7, 0.0	33.3, 66.7	-25.0, 0.0
	Min, Max	17, 83	-25, 17	0, 75	-50, 25

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.7 (21.84)		87.1 (14.23)	
	Median	100.0		86.7	
	Q1, Q3	70.0, 100.0		86.7, 93.3	
	Min, Max	47, 100		47, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	87.3 (18.18)	2.0 (11.78)	77.3 (22.65)	-8.9 (13.25)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 93.3	-13.3, 0.0
	Min, Max	53, 100	-20, 27	20, 100	-40, 13
Cycle 3	n	10	10	12	12
	Mean (SD)	88.0 (19.58)	2.7 (10.04)	73.9 (21.36)	-14.4 (11.66)
	Median	100.0	0.0	80.0	-10.0
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 86.7	-26.7, -6.7
	Min, Max	47, 100	-7, 27	20, 100	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.9 (23.67)	2.2 (14.53)	75.6 (23.33)	-12.8 (12.86)
	Median	100.0	0.0	80.0	-13.3
	Q1, Q3	86.7, 100.0	0.0, 0.0	66.7, 93.3	-23.3, 0.0
	Min, Max	33, 100	-20, 33	13, 100	-33, 7
Cycle 5	n	8	8	11	11
	Mean (SD)	86.7 (24.43)	-0.8 (10.95)	82.4 (15.57)	-9.7 (13.78)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	-3.3, 0.0	66.7, 100.0	-26.7, 0.0
	Min, Max	33, 100	-20, 20	60, 100	-27, 13
Cycle 6	n	7	7	9	9
	Mean (SD)	94.3 (15.12)	1.9 (5.04)	83.7 (12.96)	-8.9 (11.55)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	100.0, 100.0	0.0, 0.0	80.0, 93.3	-13.3, 0.0
	Min, Max	60, 100	0, 13	60, 100	-27, 7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	82.9 (27.72)	-2.9 (8.48)	89.5 (12.68)	-4.8 (10.69)
	Median	100.0	0.0	93.3	0.0
	Q1, Q3	53.3, 100.0	-6.7, 0.0	80.0, 100.0	-6.7, 0.0
	Min, Max	33, 100	-20, 7	67, 100	-27, 7
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (35.69)	-8.3 (8.39)	86.7 (26.67)	-6.7 (26.67)
	Median	70.0	-6.7	100.0	0.0
	Q1, Q3	36.7, 96.7	-13.3, -3.3	86.7, 100.0	0.0, 6.7
	Min, Max	27, 100	-20, 0	33, 100	-60, 13
Cycle 12	n	3	3	5	5
	Mean (SD)	64.4 (30.79)	-2.2 (3.85)	85.3 (15.20)	-6.7 (13.33)
	Median	46.7	0.0	86.7	0.0
	Q1, Q3	46.7, 100.0	-6.7, 0.0	73.3, 100.0	-13.3, 0.0
	Min, Max	47, 100	-7, 0	67, 100	-27, 7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	91.1 (7.70)	24.4 (21.43)	88.9 (13.88)	-4.4 (13.88)
	Median	86.7	33.3	93.3	0.0
	Q1, Q3	86.7, 100.0	0.0, 40.0	73.3, 100.0	-20.0, 6.7
	Min, Max	87, 100	0, 40	73, 100	-20, 7
Cycle 16	n	3	3	2	2
	Mean (SD)	75.6 (23.41)	8.9 (15.40)	83.3 (23.57)	-10.0 (23.57)
	Median	73.3	0.0	83.3	-10.0
	Q1, Q3	53.3, 100.0	0.0, 26.7	66.7, 100.0	-26.7, 6.7
	Min, Max	53, 100	0, 27	67, 100	-27, 7
Cycle 18	n	3	3	3	3
	Mean (SD)	73.3 (24.04)	6.7 (11.55)	75.6 (10.18)	-15.6 (13.88)
	Median	66.7	0.0	73.3	-20.0
	Q1, Q3	53.3, 100.0	0.0, 20.0	66.7, 86.7	-26.7, 0.0
	Min, Max	53, 100	0, 20	67, 87	-27, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	77.8 (23.41)	11.1 (19.25)	82.2 (13.88)	-8.9 (15.40)
	Median	80.0	0.0	86.7	0.0
	Q1, Q3	53.3, 100.0	0.0, 33.3	66.7, 93.3	-26.7, 0.0
	Min, Max	53, 100	0, 33	67, 93	-27, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	73.3 (30.55)	6.7 (24.04)	93.3 (6.67)	2.2 (3.85)
	Median	80.0	0.0	93.3	0.0
	Q1, Q3	40.0, 100.0	-13.3, 33.3	86.7, 100.0	0.0, 6.7
	Min, Max	40, 100	-13, 33	87, 100	0, 7
Cycle 24	n	2	2	3	3
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	82.2 (10.18)	-8.9 (13.88)
	Median	90.0	16.7	80.0	-13.3
	Q1, Q3	80.0, 100.0	0.0, 33.3	73.3, 93.3	-20.0, 6.7
	Min, Max	80, 100	0, 33	73, 93	-20, 7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	86.7 (18.86)	13.3 (18.86)	90.0 (4.71)	0.0 (9.43)
	Median	86.7	13.3	90.0	0.0
	Q1, Q3	73.3, 100.0	0.0, 26.7	86.7, 93.3	-6.7, 6.7
	Min, Max	73, 100	0, 27	87, 93	-7, 7
Cycle 28	n	2	2	1	1
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	100.0 (NE)	6.7 (NE)
	Median	90.0	16.7	100.0	6.7
	Q1, Q3	80.0, 100.0	0.0, 33.3	100.0, 100.0	6.7, 6.7
	Min, Max	80, 100	0, 33	100, 100	7, 7
Cycle 30	n	2	2	1	1
	Mean (SD)	76.7 (14.14)	26.7 (18.86)	100.0 (NE)	6.7 (NE)
	Median	76.7	26.7	100.0	6.7
	Q1, Q3	66.7, 86.7	13.3, 40.0	100.0, 100.0	6.7, 6.7
	Min, Max	67, 87	13, 40	100, 100	7, 7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	70.0 (23.57)	20.0 (28.28)	93.3 (NE)	0.0 (NE)
	Median	70.0	20.0	93.3	0.0
	Q1, Q3	53.3, 86.7	0.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	53, 87	0, 40	93, 93	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	60.0 (37.71)	10.0 (42.43)	93.3 (NE)	0.0 (NE)
	Median	60.0	10.0	93.3	0.0
	Q1, Q3	33.3, 86.7	-20.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	33, 87	-20, 40	93, 93	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			100.0 (NE)	6.7 (NE)
	Median			100.0	6.7
	Q1, Q3			100.0, 100.0	6.7, 6.7
	Min, Max			100, 100	7, 7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			86.7 (NE)	-6.7 (NE)
	Median			86.7	-6.7
	Q1, Q3			86.7, 86.7	-6.7, -6.7
	Min, Max			87, 87	-7, -7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	89.6 (9.49)	0.7 (20.40)	71.4 (27.23)	-14.8 (17.77)
	Median	86.7	0.0	83.3	-6.7
	Q1, Q3	86.7, 100.0	-13.3, 0.0	60.0, 86.7	-26.7, 0.0
	Min, Max	73, 100	-27, 33	7, 100	-53, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	76.7 (25.66)	-10.0 (9.64)	60.4 (23.39)	-26.7 (15.63)
	Median	83.3	-6.7	66.7	-26.7
	Q1, Q3	63.3, 96.7	-20.0, 0.0	46.7, 80.0	-33.3, -13.3
	Min, Max	27, 100	-27, 0	7, 87	-60, -7

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.1 (21.12)		79.4 (26.70)	
	Median	100.0		100.0	
	Q1, Q3	75.0, 100.0		66.7, 100.0	
	Min, Max	33, 100		17, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	88.3 (17.66)	3.3 (7.03)	71.1 (31.16)	-8.9 (18.76)
	Median	100.0	0.0	83.3	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 17	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	88.3 (22.29)	3.3 (10.54)	70.8 (29.41)	-9.7 (18.06)
	Median	100.0	0.0	75.0	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 91.7	-16.7, 0.0
	Min, Max	33, 100	0, 33	0, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	83.3 (33.33)	-1.9 (26.93)	70.8 (32.66)	-9.7 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	85.4 (27.37)	-2.1 (5.89)	78.8 (21.20)	-7.6 (18.80)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	90.5 (25.20)	0.0 (0.00)	79.6 (18.22)	-7.4 (16.90)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	0, 0	50, 100	-33, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	83.3 (28.87)	-2.4 (6.30)	95.2 (12.60)	0.0 (19.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	50.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-17, 0	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	58.3 (50.00)	-16.7 (19.25)	88.9 (27.22)	-5.6 (32.77)
	Median	66.7	-16.7	100.0	0.0
	Q1, Q3	16.7, 100.0	-33.3, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	55.6 (50.92)	-11.1 (19.25)	73.3 (30.28)	-20.0 (21.73)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	0.0, 100.0	-33.3, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-50, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	16.7 (16.67)	83.3 (28.87)	-16.7 (28.87)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	50.0, 100.0	-50.0, 0.0
	Min, Max	67, 100	0, 33	50, 100	-50, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	66.7 (33.33)	0.0 (0.00)	83.3 (23.57)	-16.7 (23.57)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	33.3, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	0, 0	67, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (38.49)	-11.1 (19.25)	88.9 (19.25)	-11.1 (19.25)
	Median	33.3	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	55.6 (50.92)	-11.1 (50.92)	88.9 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-67, 33	67, 100	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	72.2 (25.46)	5.6 (25.46)	83.3 (16.67)	-16.7 (16.67)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	50.0, 100.0	-16.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	50, 100	-17, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	83.3 (16.67)	-16.7 (16.67)
	Median	83.3	16.7	83.3	-16.7
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	100.0 (0.00)	0.0 (0.00)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 33	100, 100	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	100.0 (NE)	0.0 (NE)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 33	100, 100	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	66.7 (0.00)	16.7 (23.57)	100.0 (NE)	0.0 (NE)
	Median	66.7	16.7	100.0	0.0
	Q1, Q3	66.7, 66.7	0.0, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	67, 67	0, 33	100, 100	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	33.3 (47.14)	-16.7 (70.71)	100.0 (NE)	0.0 (NE)
	Median	33.3	-16.7	100.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	0, 67	-67, 33	100, 100	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	0.0 (47.14)	100.0 (NE)	0.0 (NE)
	Median	50.0	0.0	100.0	0.0
	Q1, Q3	33.3, 66.7	-33.3, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-33, 33	100, 100	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-16.7 (NE)
	Median			83.3	-16.7
	Q1, Q3			83.3, 83.3	-16.7, -16.7
	Min, Max			83, 83	-17, -17
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
End of Treatment	n	9	9	14	14
	Mean (SD)	87.0 (16.20)	0.0 (22.05)	67.9 (30.29)	-9.5 (15.63)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	67, 100	-33, 33	0, 100	-50, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	69.4 (36.81)	-16.7 (20.10)	53.9 (29.77)	-25.5 (18.74)
	Median	75.0	-16.7	66.7	-33.3
	Q1, Q3	58.3, 100.0	-25.0, 0.0	33.3, 66.7	-33.3, -16.7
	Min, Max	0, 100	-67, 0	0, 100	-67, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	72.9 (27.55)		75.5 (20.08)	
	Median	83.3		75.0	
	Q1, Q3	62.5, 87.5		66.7, 91.7	
	Min, Max	8, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	90.8 (9.98)	15.8 (19.42)	73.9 (19.89)	-1.1 (22.90)
	Median	91.7	8.3	75.0	0.0
	Q1, Q3	83.3, 100.0	8.3, 16.7	66.7, 83.3	-16.7, 0.0
	Min, Max	75, 100	0, 67	17, 100	-25, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	94.2 (11.15)	19.2 (23.59)	75.0 (12.31)	0.7 (17.21)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	91.7, 100.0	8.3, 16.7	66.7, 83.3	-8.3, 8.3
	Min, Max	67, 100	0, 83	50, 100	-25, 42

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	87.0 (20.46)	13.0 (17.73)	75.0 (22.47)	0.7 (16.84)
	Median	100.0	16.7	79.2	0.0
	Q1, Q3	83.3, 100.0	0.0, 16.7	62.5, 91.7	-8.3, 8.3
	Min, Max	42, 100	-17, 42	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	89.6 (15.27)	14.6 (15.91)	75.8 (19.17)	0.8 (22.19)
	Median	95.8	12.5	83.3	0.0
	Q1, Q3	83.3, 100.0	4.2, 16.7	66.7, 83.3	-8.3, 16.7
	Min, Max	58, 100	0, 50	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	10.7 (7.93)	77.8 (18.63)	-2.8 (18.16)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 16.7	66.7, 91.7	-16.7, 8.3
	Min, Max	67, 100	0, 17	42, 100	-25, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	89.3 (14.20)	15.5 (20.65)	86.9 (10.60)	3.6 (10.60)
	Median	100.0	16.7	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 16.7	83.3, 91.7	0.0, 8.3
	Min, Max	67, 100	0, 58	67, 100	-8, 25
Cycle 10	n	4	4	6	6
	Mean (SD)	79.2 (14.43)	16.7 (28.87)	86.1 (26.70)	2.8 (21.52)
	Median	79.2	8.3	100.0	4.2
	Q1, Q3	66.7, 91.7	0.0, 33.3	83.3, 100.0	0.0, 8.3
	Min, Max	67, 92	-8, 58	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	94.4 (9.62)	38.9 (47.39)	81.7 (27.89)	1.7 (23.86)
	Median	100.0	25.0	91.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 91.7	83.3, 100.0	0.0, 8.3
	Min, Max	83, 100	0, 92	33, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	86.1 (12.73)	30.6 (33.68)	80.6 (12.73)	0.0 (16.67)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 66.7	66.7, 91.7	-16.7, 16.7
	Min, Max	75, 100	0, 67	67, 92	-17, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (35.36)	-12.5 (17.68)
	Median	66.7	8.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	0.0, 58.3	41.7, 91.7	-25.0, 0.0
	Min, Max	67, 100	0, 58	42, 92	-25, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	80.6 (17.35)	25.0 (30.05)	83.3 (16.67)	-2.8 (4.81)
	Median	75.0	16.7	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 58.3	66.7, 100.0	-8.3, 0.0
	Min, Max	67, 100	0, 58	67, 100	-8, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	38.9 (37.58)	86.1 (24.06)	0.0 (8.33)
	Median	100.0	41.7	100.0	0.0
	Q1, Q3	83.3, 100.0	0.0, 75.0	58.3, 100.0	-8.3, 8.3
	Min, Max	83, 100	0, 75	58, 100	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (8.33)	-19.4 (24.06)
	Median	66.7	8.3	66.7	-33.3
	Q1, Q3	66.7, 100.0	0.0, 58.3	58.3, 75.0	-33.3, 8.3
	Min, Max	67, 100	0, 58	58, 75	-33, 8
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	4.2 (5.89)	75.0 (0.00)	-11.1 (17.35)
	Median	83.3	4.2	75.0	-16.7
	Q1, Q3	66.7, 100.0	0.0, 8.3	75.0, 75.0	-25.0, 8.3
	Min, Max	67, 100	0, 8	75, 75	-25, 8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	91.7 (11.79)	12.5 (17.68)	79.2 (17.68)	-16.7 (23.57)
	Median	91.7	12.5	79.2	-16.7
	Q1, Q3	83.3, 100.0	0.0, 25.0	66.7, 91.7	-33.3, 0.0
	Min, Max	83, 100	0, 25	67, 92	-33, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	87.5 (17.68)	8.3 (11.79)	83.3 (NE)	-8.3 (NE)
	Median	87.5	8.3	83.3	-8.3
	Q1, Q3	75.0, 100.0	0.0, 16.7	83.3, 83.3	-8.3, -8.3
	Min, Max	75, 100	0, 17	83, 83	-8, -8
Cycle 30	n	2	2	1	1
	Mean (SD)	83.3 (11.79)	50.0 (47.14)	83.3 (NE)	-8.3 (NE)
	Median	83.3	50.0	83.3	-8.3
	Q1, Q3	75.0, 91.7	16.7, 83.3	83.3, 83.3	-8.3, -8.3
	Min, Max	75, 92	17, 83	83, 83	-8, -8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	70.8 (5.89)	37.5 (41.25)	83.3 (NE)	-8.3 (NE)
	Median	70.8	37.5	83.3	-8.3
	Q1, Q3	66.7, 75.0	8.3, 66.7	83.3, 83.3	-8.3, -8.3
	Min, Max	67, 75	8, 67	83, 83	-8, -8
Cycle 34	n	2	2	1	1
	Mean (SD)	75.0 (35.36)	41.7 (0.00)	66.7 (NE)	-25.0 (NE)
	Median	75.0	41.7	66.7	-25.0
	Q1, Q3	50.0, 100.0	41.7, 41.7	66.7, 66.7	-25.0, -25.0
	Min, Max	50, 100	42, 42	67, 67	-25, -25
Cycle 36	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-8.3 (NE)
	Median			83.3	-8.3
	Q1, Q3			83.3, 83.3	-8.3, -8.3
	Min, Max			83, 83	-8, -8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-8.3 (NE)
	Median			83.3	-8.3
	Q1, Q3			83.3, 83.3	-8.3, -8.3
	Min, Max			83, 83	-8, -8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
End of Treatment	n	9	9	14	14
	Mean (SD)	88.0 (15.09)	6.5 (24.92)	72.6 (22.75)	-5.4 (17.17)
	Median	91.7	8.3	75.0	0.0
	Q1, Q3	91.7, 100.0	0.0, 16.7	66.7, 91.7	-25.0, 8.3
	Min, Max	58, 100	-42, 42	25, 100	-33, 25

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	70.8 (23.44)	-2.1 (18.84)	58.8 (19.43)	-16.7 (13.82)
	Median	75.0	0.0	66.7	-16.7
	Q1, Q3	62.5, 87.5	-12.5, 8.3	41.7, 75.0	-25.0, -8.3
	Min, Max	17, 100	-42, 33	17, 83	-33, 8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	94.4 (14.79)		78.4 (18.41)	
	Median	100.0		83.3	
	Q1, Q3	100.0, 100.0		66.7, 100.0	
	Min, Max	50, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	93.3 (11.65)	0.0 (17.57)	75.6 (28.78)	-1.1 (17.21)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-33, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	91.7 (21.15)	-1.7 (9.46)	80.6 (17.16)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-8.3, 0.0
	Min, Max	33, 100	-17, 17	50, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	94.4 (11.79)	1.9 (10.02)	80.6 (24.45)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	75.0, 100.0	0.0, 16.7
	Min, Max	67, 100	-17, 17	33, 100	-50, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	87.5 (23.15)	-6.3 (17.68)	83.3 (26.87)	0.0 (27.89)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 16.7
	Min, Max	50, 100	-50, 0	33, 100	-50, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	92.9 (18.90)	0.0 (0.00)	83.3 (16.67)	0.0 (16.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	50, 100	-33, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	90.5 (16.27)	-2.4 (15.00)	90.5 (13.11)	7.1 (16.27)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	67, 100	-33, 17	67, 100	-17, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	87.5 (25.00)	0.0 (0.00)	83.3 (25.82)	0.0 (18.26)
	Median	100.0	0.0	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	33, 100	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	77.8 (38.49)	-5.6 (9.62)	73.3 (27.89)	-6.7 (27.89)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	33.3, 100.0	-16.7, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	77.8 (19.25)	0.0 (0.00)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	66.7 (47.14)	-16.7 (23.57)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 16.7	33.3, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 17	33, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	88.9 (9.62)	5.6 (25.46)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	83.3, 100.0	-16.7, 33.3	66.7, 100.0	0.0, 0.0
	Min, Max	83, 100	-17, 33	67, 100	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	83, 100	0, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (0.00)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (NE)	0.0 (NE)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (NE)	0.0 (NE)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	75.0 (11.79)	0.0 (23.57)	100.0 (NE)	0.0 (NE)
	Median	75.0	0.0	100.0	0.0
	Q1, Q3	66.7, 83.3	-16.7, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 83	-17, 17	100, 100	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (NE)	0.0 (NE)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-16.7 (NE)
	Median			83.3	-16.7
	Q1, Q3			83.3, 83.3	-16.7, -16.7
	Min, Max			83, 83	-17, -17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	98.1 (5.56)	5.6 (11.79)	73.8 (29.03)	-4.8 (18.98)
	Median	100.0	0.0	75.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	83, 100	0, 33	0, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	84.7 (24.06)	-9.7 (19.41)	61.8 (27.49)	-16.7 (19.54)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	-25.0, 0.0	33.3, 83.3	-33.3, 0.0
	Min, Max	33, 100	-50, 17	0, 100	-50, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	83.3 (21.32)		80.4 (17.91)	
	Median	91.7		83.3	
	Q1, Q3	66.7, 100.0		66.7, 100.0	
	Min, Max	33, 100		50, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	85.0 (18.34)	0.0 (15.71)	68.9 (28.08)	-10.0 (23.40)
	Median	91.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	-17, 33	0, 100	-67, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	90.0 (17.92)	5.0 (11.25)	76.4 (21.86)	-6.9 (19.41)
	Median	100.0	0.0	75.0	-8.3
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 33	33, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.2 (17.57)	0.0 (16.67)	69.4 (25.46)	-13.9 (19.89)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 0.0	50.0, 91.7	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	91.7 (15.43)	0.0 (17.82)	71.2 (24.82)	-15.2 (22.92)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-50, 17
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	4.8 (12.60)	83.3 (16.67)	-5.6 (18.63)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	85.7 (17.82)	-4.8 (23.00)	88.1 (15.85)	-2.4 (20.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	-33, 33	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (43.03)	-41.7 (41.94)	83.3 (27.89)	-5.6 (25.09)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	16.7, 83.3	-66.7, -16.7	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-100, 0	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	83.3 (28.87)	-3.3 (24.72)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	33, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 0	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	58.3 (35.36)	-25.0 (11.79)
	Median	66.7	0.0	58.3	-25.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	33.3, 83.3	-33.3, -16.7
	Min, Max	67, 100	-33, 0	33, 83	-33, -17
Cycle 18	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	66.7 (33.33)	-22.2 (38.49)	83.3 (16.67)	-5.6 (9.62)
	Median	66.7	0.0	83.3	0.0
	Q1, Q3	33.3, 100.0	-66.7, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-67, 0	67, 100	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	77.8 (19.25)	-11.1 (19.25)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	91.7 (11.79)	-8.3 (11.79)
	Median	83.3	0.0	91.7	-8.3
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	83, 100	-17, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	66.7 (NE)	-33.3 (NE)
	Median	83.3	0.0	66.7	-33.3
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 66.7	-33.3, -33.3
	Min, Max	67, 100	0, 0	67, 67	-33, -33
Cycle 30	n	2	2	1	1
	Mean (SD)	66.7 (0.00)	-16.7 (23.57)	83.3 (NE)	-16.7 (NE)
	Median	66.7	-16.7	83.3	-16.7
	Q1, Q3	66.7, 66.7	-33.3, 0.0	83.3, 83.3	-16.7, -16.7
	Min, Max	67, 67	-33, 0	83, 83	-17, -17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	-33.3 (47.14)	100.0 (NE)	0.0 (NE)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	33.3, 66.7	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-67, 0	100, 100	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	-33.3 (47.14)	100.0 (NE)	0.0 (NE)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	33.3, 66.7	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-67, 0	100, 100	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
End of Treatment	n	9	9	14	14
	Mean (SD)	87.0 (20.03)	7.4 (16.90)	69.0 (35.12)	-11.9 (26.50)
	Median	100.0	0.0	75.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	-33.3, 0.0
	Min, Max	50, 100	-17, 33	0, 100	-67, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	65.3 (29.69)	-18.1 (29.69)	51.0 (27.30)	-29.4 (18.19)
	Median	66.7	-16.7	66.7	-33.3
	Q1, Q3	50.0, 91.7	-25.0, 0.0	33.3, 66.7	-33.3, -16.7
	Min, Max	0, 100	-100, 17	0, 100	-67, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	24.1 (31.72)		33.3 (22.57)	
	Median	5.6		33.3	
	Q1, Q3	0.0, 50.0		22.2, 44.4	
	Min, Max	0, 89		0, 78	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.6 (21.72)	-8.9 (23.31)	41.5 (26.05)	9.6 (18.24)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-11.1, 0.0	22.2, 44.4	0.0, 22.2
	Min, Max	0, 56	-67, 22	0, 100	-11, 56
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (25.01)	-4.4 (15.89)	39.8 (23.43)	8.3 (13.50)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 44.4	-11.1, 0.0	27.8, 55.6	0.0, 16.7
	Min, Max	0, 67	-44, 11	11, 89	-11, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	23.5 (30.65)	-1.2 (10.31)	42.6 (28.36)	11.1 (22.72)
	Median	11.1	0.0	44.4	5.6
	Q1, Q3	0.0, 33.3	0.0, 0.0	16.7, 61.1	0.0, 33.3
	Min, Max	0, 89	-22, 11	0, 89	-33, 44
Cycle 5	n	8	8	11	11
	Mean (SD)	15.3 (25.85)	-5.6 (10.29)	32.3 (26.04)	5.1 (20.71)
	Median	0.0	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	-11.1, 0.0	11.1, 44.4	0.0, 22.2
	Min, Max	0, 67	-22, 0	0, 89	-44, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	12.7 (25.20)	1.6 (4.20)	29.6 (21.52)	1.2 (15.16)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 22.2	0.0, 0.0	22.2, 33.3	-11.1, 11.1
	Min, Max	0, 67	0, 11	0, 78	-22, 22

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	25.4 (36.69)	1.6 (7.67)	11.1 (15.71)	-12.7 (16.27)
	Median	0.0	0.0	0.0	-11.1
	Q1, Q3	0.0, 77.8	0.0, 11.1	0.0, 33.3	-22.2, 0.0
	Min, Max	0, 78	-11, 11	0, 33	-44, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (46.70)	8.3 (18.98)	18.5 (30.36)	-9.3 (25.74)
	Median	50.0	5.6	5.6	-11.1
	Q1, Q3	11.1, 88.9	-5.6, 22.2	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 100	-11, 33	0, 78	-44, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	40.7 (52.51)	-11.1 (50.92)	33.3 (15.71)	0.0 (11.11)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	33.3, 33.3	-11.1, 11.1
	Min, Max	0, 100	-67, 33	11, 56	-11, 11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (11.11)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-22.2, 0.0
	Min, Max	0, 33	-56, 0	11, 33	-22, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	29.6 (33.95)	-22.2 (38.49)	33.3 (31.43)	0.0 (15.71)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	11.1, 55.6	-11.1, 11.1
	Min, Max	0, 67	-67, 0	11, 56	-11, 11
Cycle 18	n	3	3	3	3
	Mean (SD)	37.0 (39.02)	-14.8 (16.97)	25.9 (16.97)	-7.4 (6.42)
	Median	33.3	-11.1	22.2	-11.1
	Q1, Q3	0.0, 77.8	-33.3, 0.0	11.1, 44.4	-11.1, 0.0
	Min, Max	0, 78	-33, 0	11, 44	-11, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (0.00)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-11.1, -11.1
	Min, Max	0, 33	-56, 0	11, 33	-11, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (22.22)	-29.6 (25.66)	37.0 (6.42)	3.7 (6.42)
	Median	22.2	-44.4	33.3	0.0
	Q1, Q3	0.0, 44.4	-44.4, 0.0	33.3, 44.4	0.0, 11.1
	Min, Max	0, 44	-44, 0	33, 44	0, 11
Cycle 24	n	2	2	3	3
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	37.0 (12.83)	3.7 (16.97)
	Median	11.1	-22.2	44.4	0.0
	Q1, Q3	0.0, 22.2	-44.4, 0.0	22.2, 44.4	-11.1, 22.2
	Min, Max	0, 22	-44, 0	22, 44	-11, 22

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	16.7 (7.86)	-11.1 (0.00)
	Median	11.1	-22.2	16.7	-11.1
	Q1, Q3	0.0, 22.2	-44.4, 0.0	11.1, 22.2	-11.1, -11.1
	Min, Max	0, 22	-44, 0	11, 22	-11, -11
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	33.3 (NE)	11.1 (NE)
	Median	16.7	-16.7	33.3	11.1
	Q1, Q3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	11.1, 11.1
	Min, Max	0, 33	-33, 0	33, 33	11, 11
Cycle 30	n	2	2	1	1
	Mean (SD)	33.3 (0.00)	-44.4 (15.71)	11.1 (NE)	-11.1 (NE)
	Median	33.3	-44.4	11.1	-11.1
	Q1, Q3	33.3, 33.3	-55.6, -33.3	11.1, 11.1	-11.1, -11.1
	Min, Max	33, 33	-56, -33	11, 11	-11, -11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	61.1 (55.00)	-16.7 (39.28)	22.2 (NE)	0.0 (NE)
	Median	61.1	-16.7	22.2	0.0
	Q1, Q3	22.2, 100.0	-44.4, 11.1	22.2, 22.2	0.0, 0.0
	Min, Max	22, 100	-44, 11	22, 22	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	55.6 (31.43)	-22.2 (15.71)	33.3 (NE)	11.1 (NE)
	Median	55.6	-22.2	33.3	11.1
	Q1, Q3	33.3, 77.8	-33.3, -11.1	33.3, 33.3	11.1, 11.1
	Min, Max	33, 78	-33, -11	33, 33	11, 11
Cycle 36	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
End of Treatment	n	9	9	14	14
	Mean (SD)	18.5 (14.70)	1.2 (18.79)	42.1 (25.48)	8.7 (16.98)
	Median	22.2	0.0	33.3	5.6
	Q1, Q3	0.0, 33.3	0.0, 11.1	22.2, 66.7	0.0, 22.2
	Min, Max	0, 33	-33, 22	0, 89	-22, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.0 (36.22)	13.9 (13.50)	58.8 (26.58)	25.5 (15.60)
	Median	22.2	11.1	55.6	33.3
	Q1, Q3	11.1, 61.1	5.6, 22.2	44.4, 77.8	22.2, 33.3
	Min, Max	0, 100	-11, 33	11, 100	0, 56

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	5.6 (10.86)		8.8 (16.79)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 8.3		0.0, 16.7	
	Min, Max	0, 33		0, 50	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (13.15)	20.0 (20.12)	10.0 (13.80)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 17	0, 67	-17, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-1.7 (9.46)	15.3 (20.67)	12.5 (23.70)
	Median	0.0	0.0	8.3	8.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 25.0	0.0, 25.0
	Min, Max	0, 17	-17, 17	0, 67	-17, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (18.84)	3.7 (13.89)	11.1 (12.97)	8.3 (15.08)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 50	-17, 33	0, 33	-17, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (12.60)	2.1 (13.91)	16.7 (19.72)	13.6 (22.13)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-17, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	7.1 (13.11)	4.8 (12.60)	22.2 (18.63)	18.5 (21.15)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 50	-17, 50

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (19.25)	7.1 (8.91)	2.4 (15.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	-16.7, 16.7
	Min, Max	0, 33	-33, 33	0, 17	-17, 17
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-4.2 (28.46)	5.6 (13.61)	0.0 (10.54)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-25.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	-17, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (25.46)	10.0 (22.36)	3.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 17	0, 50	-17, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	16.7 (23.57)	8.3 (11.79)
	Median	0.0	0.0	16.7	8.3
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (9.62)	5.6 (9.62)
	Median	0.0	-8.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 17	0, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	8.3 (11.79)	8.3 (11.79)
	Median	0.0	-8.3	8.3	8.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 17	0, 17
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-17, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			16.7 (NE)	16.7 (NE)
	Median			16.7	16.7
	Q1, Q3			16.7, 16.7	16.7, 16.7
	Min, Max			17, 17	17, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			16.7 (NE)	16.7 (NE)
	Median			16.7	16.7
	Q1, Q3			16.7, 16.7	16.7, 16.7
	Min, Max			17, 17	17, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	5.6 (16.67)	3.7 (18.22)	14.3 (15.82)	4.8 (23.05)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-17, 50	0, 33	-50, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	11.1 (20.52)	5.6 (16.41)	35.3 (19.44)	26.5 (18.69)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 8.3	16.7, 50.0	16.7, 33.3
	Min, Max	0, 50	-17, 50	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	18.1 (28.83)		24.5 (31.25)	
	Median	0.0		16.7	
	Q1, Q3	0.0, 25.0		0.0, 33.3	
	Min, Max	0, 83		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.0 (11.25)	-13.3 (26.99)	24.4 (33.25)	1.1 (29.19)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 0.0
	Min, Max	0, 33	-83, 0	0, 100	-50, 83
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-15.0 (24.15)	26.4 (27.02)	5.6 (32.05)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-8.3, 16.7
	Min, Max	0, 17	-67, 0	0, 83	-50, 83

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	13.0 (28.60)	-7.4 (12.11)	20.8 (23.70)	0.0 (26.59)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 83	-33, 0	0, 83	-50, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	6.3 (17.68)	-8.3 (12.60)	21.2 (24.82)	6.1 (22.70)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-33, 0	0, 83	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (16.67)	20.4 (24.69)	5.6 (25.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-33, 50

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.13)	-11.9 (24.93)	7.1 (13.11)	2.4 (20.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-67, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (9.62)	-16.7 (33.33)	11.1 (27.22)	5.6 (32.77)
	Median	8.3	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 17	-67, 0	0, 67	-33, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	16.7 (28.87)	-16.7 (60.09)	20.0 (21.73)	13.3 (21.73)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 50.0	-83.3, 33.3	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-83, 33	0, 50	0, 50

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (16.67)	16.7 (16.67)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (9.62)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-17, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	27.8 (48.11)	-5.6 (9.62)	22.2 (9.62)	22.2 (9.62)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 83.3	-16.7, 0.0	16.7, 33.3	16.7, 33.3
	Min, Max	0, 83	-17, 0	17, 33	17, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-17, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-17, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-33.3 (23.57)	16.7 (NE)	16.7 (NE)
	Median	16.7	-33.3	16.7	16.7
	Q1, Q3	0.0, 33.3	-50.0, -16.7	16.7, 16.7	16.7, 16.7
	Min, Max	0, 33	-50, -17	17, 17	17, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	0.0 (23.57)	0.0 (NE)	0.0 (NE)
	Median	50.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-17, 17	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	25.0 (35.36)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	25.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 50	-33, -17	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (12.11)	-3.7 (23.24)	36.9 (34.70)	8.3 (29.78)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 66.7	0.0, 16.7
	Min, Max	0, 33	-50, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	26.4 (32.14)	8.3 (19.46)	50.0 (30.05)	25.5 (32.87)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 41.7	0.0, 25.0	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 83

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		15.7 (26.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	24.4 (26.63)	11.1 (20.57)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (23.57)	8.3 (23.57)	12.1 (22.47)	3.0 (10.05)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	14.8 (24.22)	3.7 (11.11)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	25.0 (31.91)	11.1 (27.22)	5.6 (13.61)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	13.3 (18.26)	6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (33.33)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 33.3
	Min, Max	0, 33	0, 33	0, 33	-33, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	11.1 (16.67)	11.1 (16.67)	28.6 (31.64)	11.9 (21.11)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	13.9 (22.29)	13.9 (22.29)	39.2 (26.97)	23.5 (22.87)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 67	0, 67	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (35.77)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 50.0		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	16.7 (28.33)	-10.0 (16.10)	28.9 (30.52)	6.7 (31.37)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 100	-67, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	13.3 (17.21)	-13.3 (39.13)	25.0 (25.13)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	11.1 (16.67)	-18.5 (33.79)	16.7 (17.41)	2.8 (22.29)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	20.8 (24.80)	-12.5 (24.80)	9.1 (21.56)	0.0 (21.08)
	Median	16.7	-16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	-9.5 (16.27)	11.1 (16.67)	3.7 (20.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	28.6 (40.50)	-9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-41.7 (41.94)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-66.7, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-100, 0	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	13.3 (29.81)	6.7 (14.91)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	44.4 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	66.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-44.4 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	-22.2 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	33.3	-33.3	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	33.3 (33.33)	22.2 (38.49)
	Median	16.7	-16.7	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	16.7 (23.57)	16.7 (23.57)
	Median	16.7	-16.7	16.7	16.7
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 33	0, 33
Cycle 28	n	2	2	1	1
	Mean (SD)	33.3 (47.14)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	33.3 (0.00)	-50.0 (23.57)	0.0 (NE)	0.0 (NE)
	Median	33.3	-50.0	0.0	0.0
	Q1, Q3	33.3, 33.3	-66.7, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	-67, -33	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	-33.3 (0.00)	0.0 (NE)	0.0 (NE)
	Median	50.0	-33.3	0.0	0.0
	Q1, Q3	33.3, 66.7	-33.3, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 67	-33, -33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	66.7 (47.14)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	66.7	-16.7	0.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	33, 100	-33, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	22.2 (33.33)	3.7 (20.03)	23.8 (33.15)	0.0 (26.15)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-33.3, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	36.1 (36.12)	13.9 (17.16)	51.0 (29.15)	29.4 (28.58)
	Median	33.3	0.0	66.7	33.3
	Q1, Q3	0.0, 50.0	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	10.0 (22.50)	-10.0 (35.31)	31.1 (34.43)	6.7 (25.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (10.54)	-16.7 (32.39)	19.4 (22.29)	5.6 (27.83)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-11.1 (33.33)	25.0 (20.72)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-12.5 (39.59)	27.3 (25.03)	15.2 (34.52)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	25.9 (22.22)	11.1 (37.27)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 0	0, 67	-67, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	-9.5 (41.79)	14.3 (26.23)	0.0 (38.49)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (16.67)	-8.3 (41.94)	11.1 (27.22)	-5.6 (32.77)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	16.7, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	-22.2 (69.39)	13.3 (29.81)	-6.7 (36.51)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-100, 33	0, 67	-67, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-44.4 (50.92)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-66.7 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, -33	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-50.0 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	-50.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, -33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-66.7 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, -33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	14.8 (17.57)	3.7 (26.06)	33.3 (34.59)	9.5 (33.15)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	-67, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.9 (34.33)	16.7 (26.59)	49.0 (29.15)	27.5 (31.70)
	Median	33.3	16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 67	0, 100	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	19.4 (33.21)		17.6 (31.44)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	3.3 (29.19)	22.2 (34.88)	2.2 (23.46)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (28.11)	0.0 (38.49)	16.7 (17.41)	13.9 (22.29)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 33	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	18.5 (33.79)	0.0 (28.87)	11.1 (16.41)	8.3 (20.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	25.0 (38.83)	16.7 (35.63)	9.1 (15.57)	9.1 (15.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 16.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.8 (17.57)	14.8 (17.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	23.8 (41.79)	14.3 (26.23)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 67	0, 0	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	33.3 (47.14)	16.7 (57.74)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-16.7, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 100	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	0.0 (66.67)	13.3 (29.81)	13.3 (29.81)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 67	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 0	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-11.1 (50.92)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 0	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	-16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	50.0	16.7	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (22.22)	-7.4 (36.43)	26.2 (37.39)	4.8 (25.68)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-100, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.9 (42.24)	19.4 (30.01)	35.3 (32.21)	17.6 (29.15)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 83.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		7.8 (14.57)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 0.0	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (14.05)	8.9 (15.26)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	10.0 (16.10)	-3.3 (18.92)	22.2 (25.95)	11.1 (21.71)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-33, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (20.03)	11.1 (21.71)	0.0 (14.21)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (15.43)	-4.2 (11.79)	15.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	0.0 (0.00)	18.5 (24.22)	11.1 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (26.23)	0.0 (19.25)	9.5 (25.20)	0.0 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (33.33)	8.3 (16.67)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	11.1 (19.25)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (14.70)	-11.1 (16.67)	2.4 (8.91)	-4.8 (12.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	19.4 (26.43)	5.6 (12.97)	23.5 (25.72)	15.7 (20.81)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Global health status / QoL									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	63.19 (29.83)	10.50 (4.57)	17	57.84 (25.08)	3.23 (3.46)	7.27 (-3.30, 17.85)	0.58 (-0.26, 1.43)	0.1680

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.67 (21.84)	-1.63 (2.77)	17	87.06 (14.23)	-10.49 (2.10)	8.86 (2.53, 15.19)	1.22 (0.30, 2.14)	0.0081

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.11 (21.12)	6.19 (4.92)	17	79.41 (26.70)	-5.03 (3.64)	11.22 (-0.36, 22.81)	0.79 (-0.04, 1.63)	0.0570

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	72.92 (27.55)	13.40 (5.91)	17	75.49 (20.08)	0.54 (4.17)	12.87 (-0.63, 26.36)	0.79 (-0.06, 1.64)	0.0606

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Cognitive functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	94.44 (14.79)	0.26 (4.26)	17	78.43 (18.41)	-0.92 (3.17)	1.18 (-9.14, 11.51)	0.11 (-0.80, 1.01)	0.8143

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	83.33 (21.32)	4.87 (5.70)	17	80.39 (17.91)	-7.60 (4.20)	12.47 (-0.85, 25.79)	0.78 (-0.07, 1.63)	0.0650

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	24.07 (31.72)	-6.22 (5.46)	17	33.33 (22.57)	5.60 (4.12)	-11.82 (-24.80, 1.15)	-0.76 (-1.60, 0.09)	0.0714

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	5.56 (10.86)	-3.70 (3.58)	17	8.82 (16.79)	9.08 (2.74)	-12.78 (-20.99, -4.57)	-1.35 (-2.29, -0.41)	0.0038

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	18.06 (28.83)	-14.62 (6.52)	17	24.51 (31.25)	3.66 (4.88)	-18.29 (-33.68, -2.89)	-0.99 (-1.87, -0.12)	0.0226

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	2.09 (3.77)	17	15.69 (26.66)	9.88 (2.85)	-7.78 (-16.92, 1.35)	-0.80 (-1.74, 0.15)	0.0907

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Insomnia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (35.77)	-9.34 (4.49)	17	21.57 (31.05)	3.01 (3.58)	-12.35 (-22.58, -2.13)	-1.11 (-2.06, -0.16)	0.0199

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Appetite loss									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	-13.72 (6.40)	17	21.57 (31.05)	2.38 (4.78)	-16.10 (-30.61, -1.59)	-0.97 (-1.88, -0.07)	0.0311

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Constipation									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	19.44 (33.21)	9.79 (6.80)	17	17.65 (31.44)	8.51 (5.01)	1.28 (-14.59, 17.15)	0.07 (-0.76, 0.90)	0.8684

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Diarrhea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-5.26 (3.06)	17	7.84 (14.57)	3.70 (2.39)	-8.96 (-15.84, -2.08)	-1.22 (-2.19, -0.25)	0.0125

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-ia.rtf

Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QoL	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.808 (0.083, 7.837)	0.8539
Physical Functioning	13	2 (15.4)	NR (2.3, NE)	17	8 (47.1)	2.1 (0.9, NE)	0.213 (0.025, 1.787)	0.1173
Role Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.4 (0.7, NE)	0.177 (0.036, 0.879)	0.0198
Emotional Functioning	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	14.7 (2.2, NE)	0.000 (0.000, NE)	0.1326
Cognitive Functioning	13	2 (15.4)	NR (1.4, NE)	17	5 (29.4)	NR (2.2, NE)	0.879 (0.155, 4.997)	0.8846
Social Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.5 (0.8, NE)	0.235 (0.047, 1.179)	0.0586

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-2-1-2-eff-tte-qlq-c30-pop1-ia.rtf

Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Fatigue	13	3 (23.1)	NR (3.7, NE)	17	11 (64.7)	2.1 (0.7, NE)	0.327 (0.079, 1.343)	0.1083
Nausea and Vomiting	13	1 (7.7)	NR (NE, NE)	17	9 (52.9)	4.4 (0.8, NE)	0.135 (0.016, 1.117)	0.0310
Pain	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	NR (2.1, NE)	0.000 (0.000, NE)	0.0539
Dyspnoea	13	3 (23.1)	NR (1.4, NE)	17	4 (23.5)	NR (1.4, NE)	1.714 (0.268, 10.985)	0.5657
Insomnia	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	19.1 (1.4, NE)	0.171 (0.020, 1.450)	0.0687
Appetite Loss	13	2 (15.4)	NR (5.3, NE)	17	8 (47.1)	3.3 (1.4, NE)	0.352 (0.067, 1.851)	0.2032

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Constipation	13	3 (23.1)	NR (0.7, NE)	17	7 (41.2)	NR (0.8, NE)	0.634 (0.150, 2.673)	0.5075
Diarrhea	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.1, NE)	0.536 (0.073, 3.928)	0.5358

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

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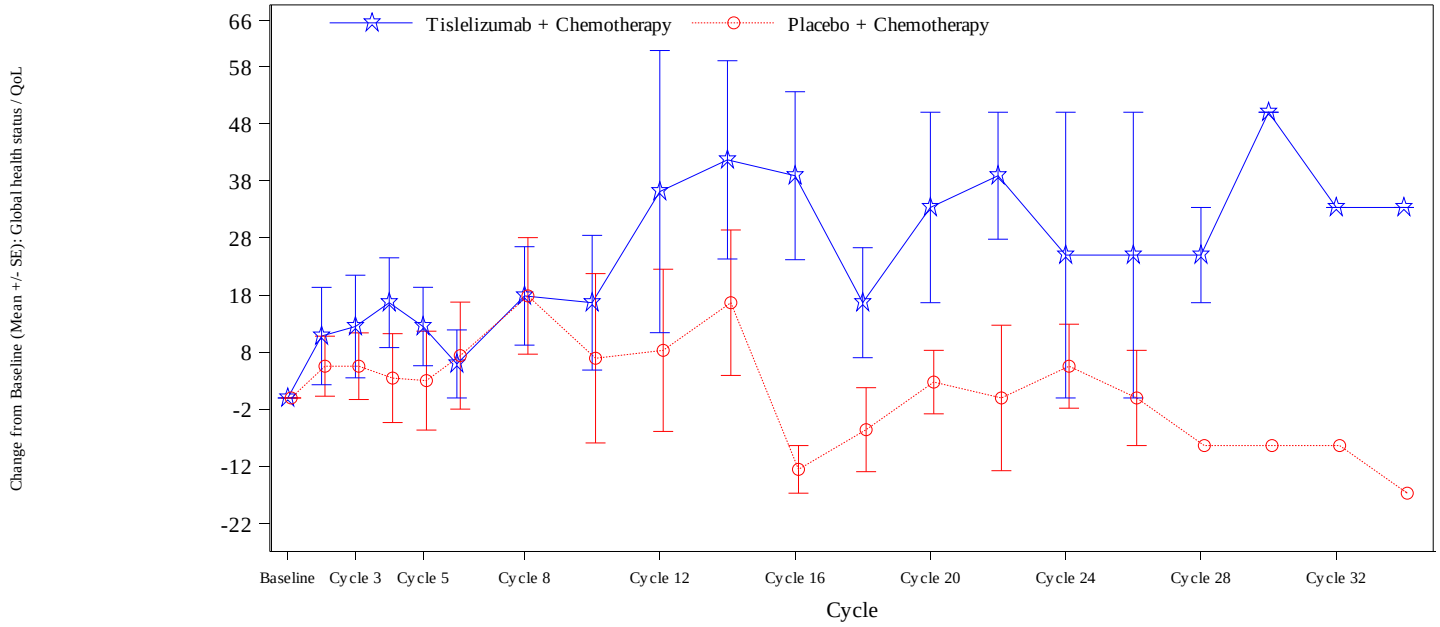
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

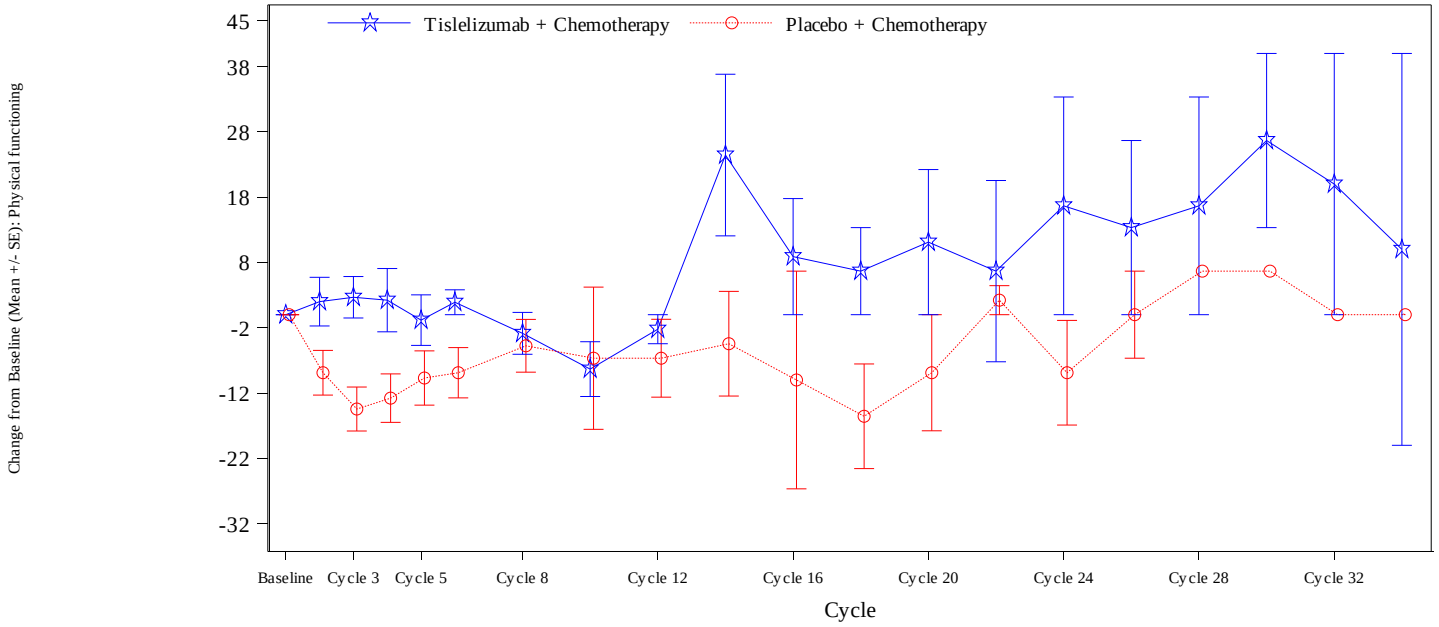


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-1-series-c30-pop1-ia.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

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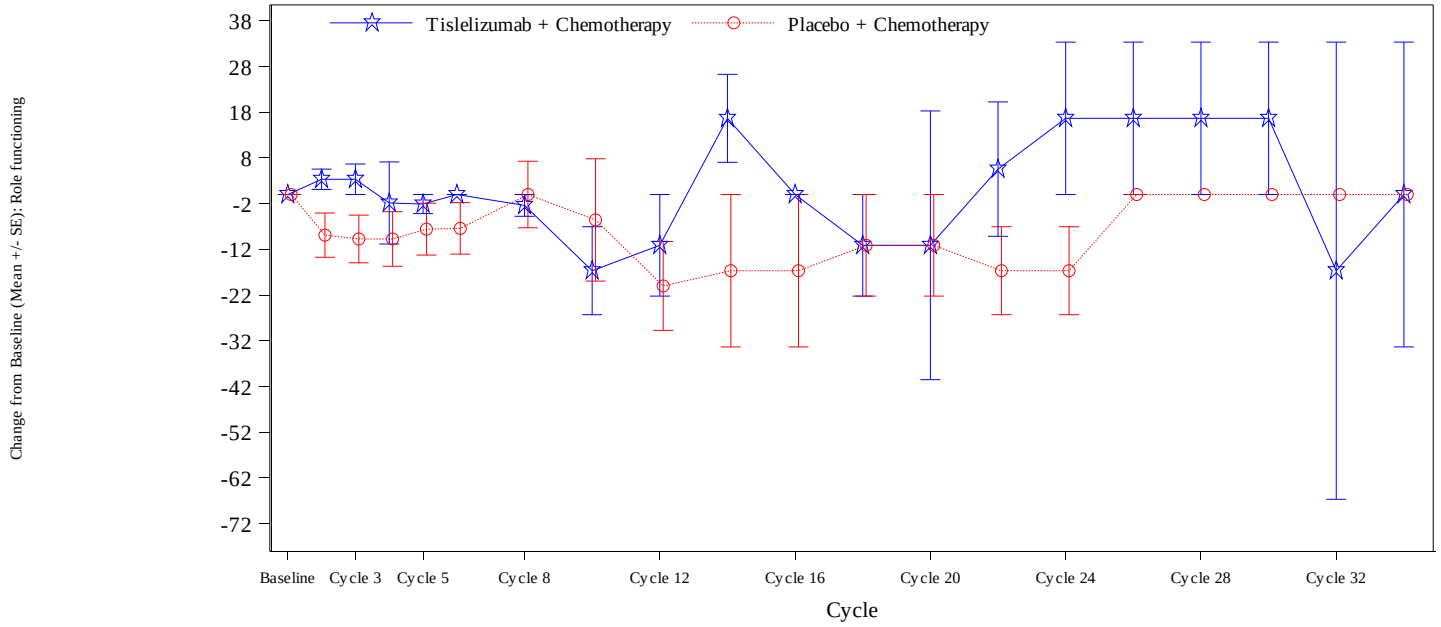
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

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Figure 14.2.7.1:
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ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

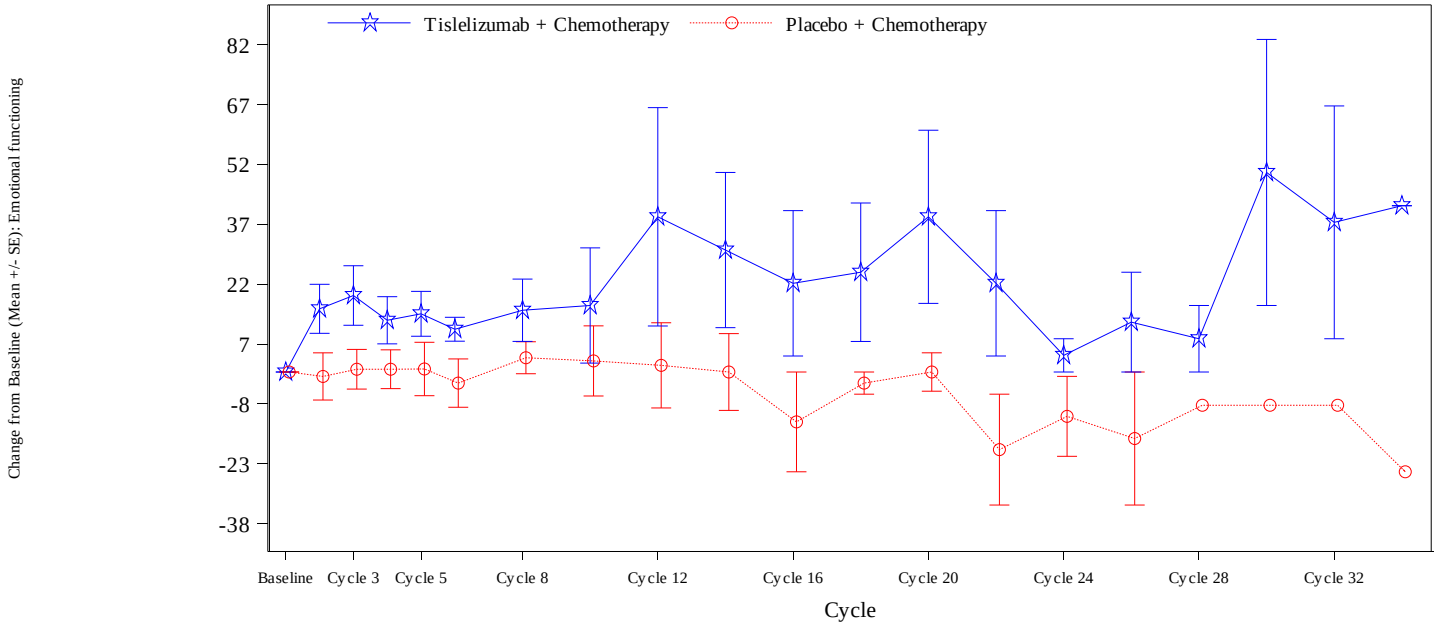

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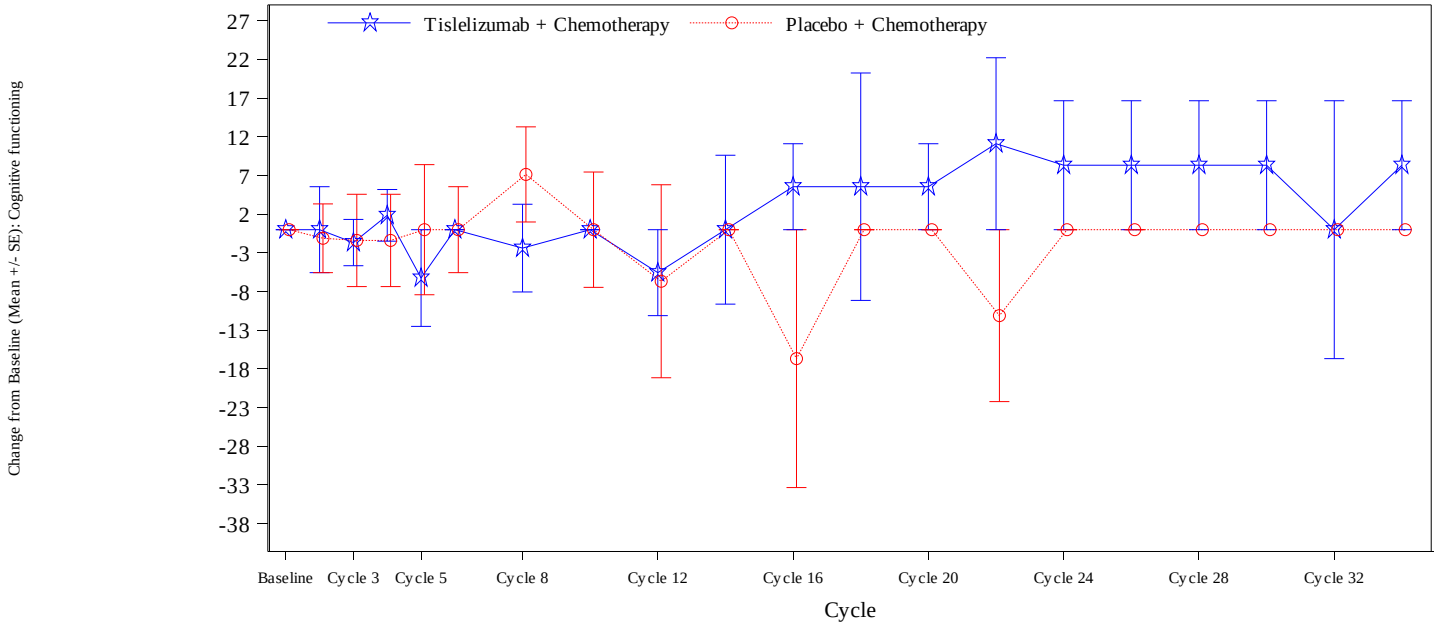
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

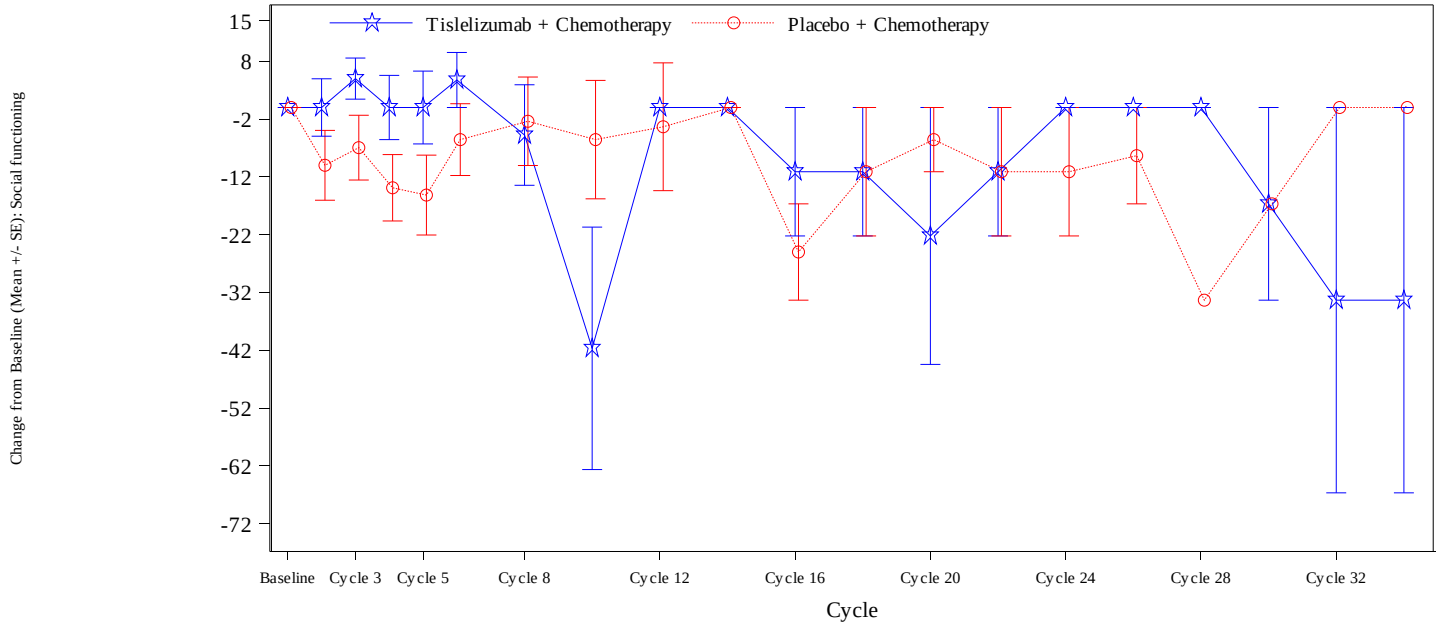

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Figure 14.2.7.1:
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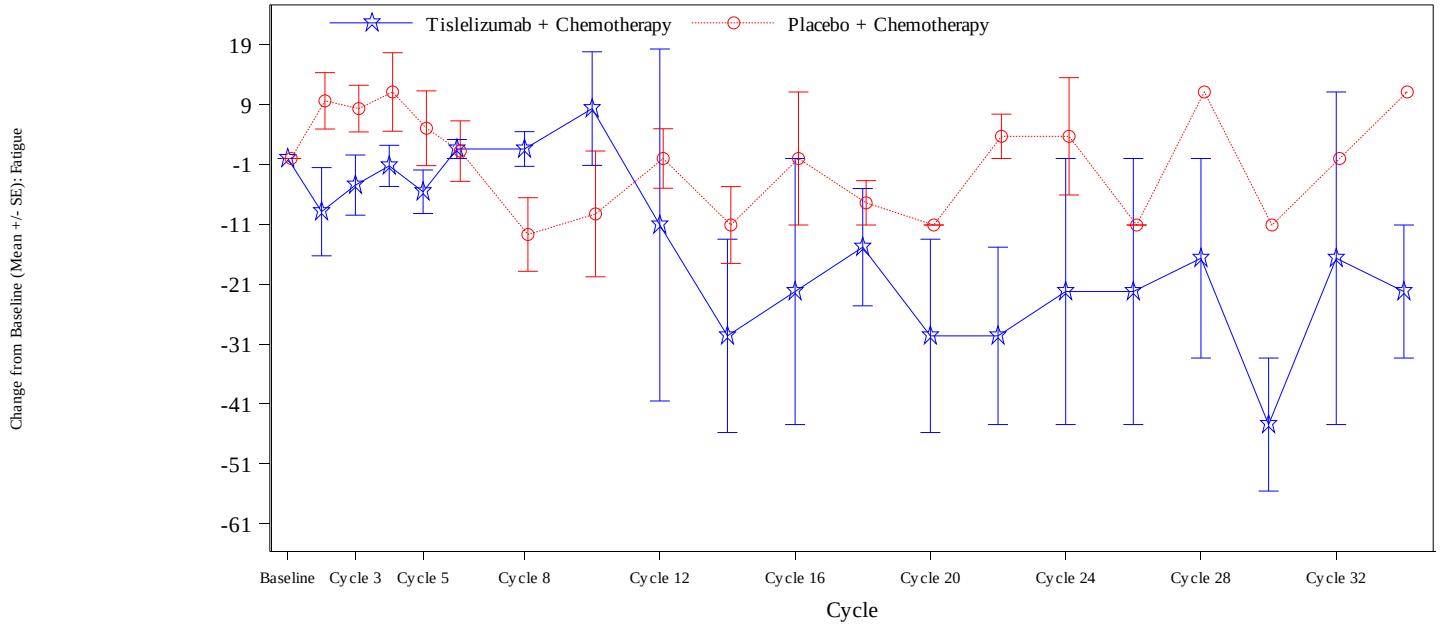

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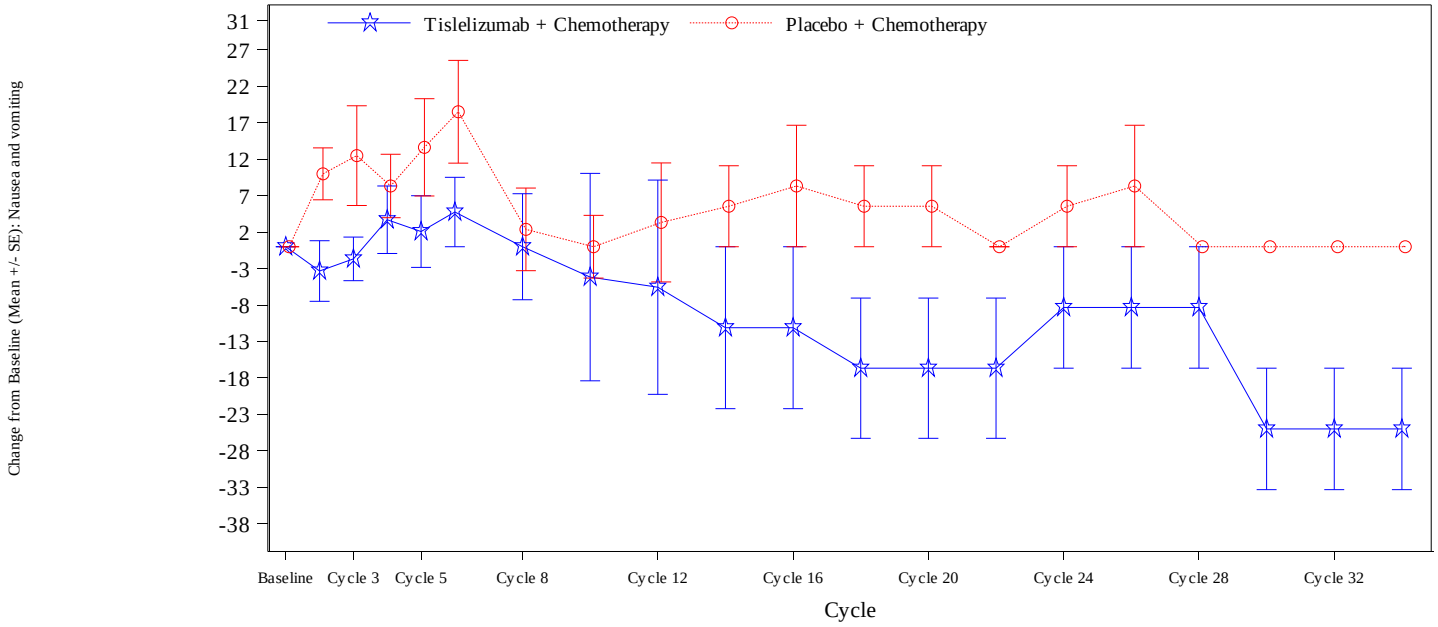
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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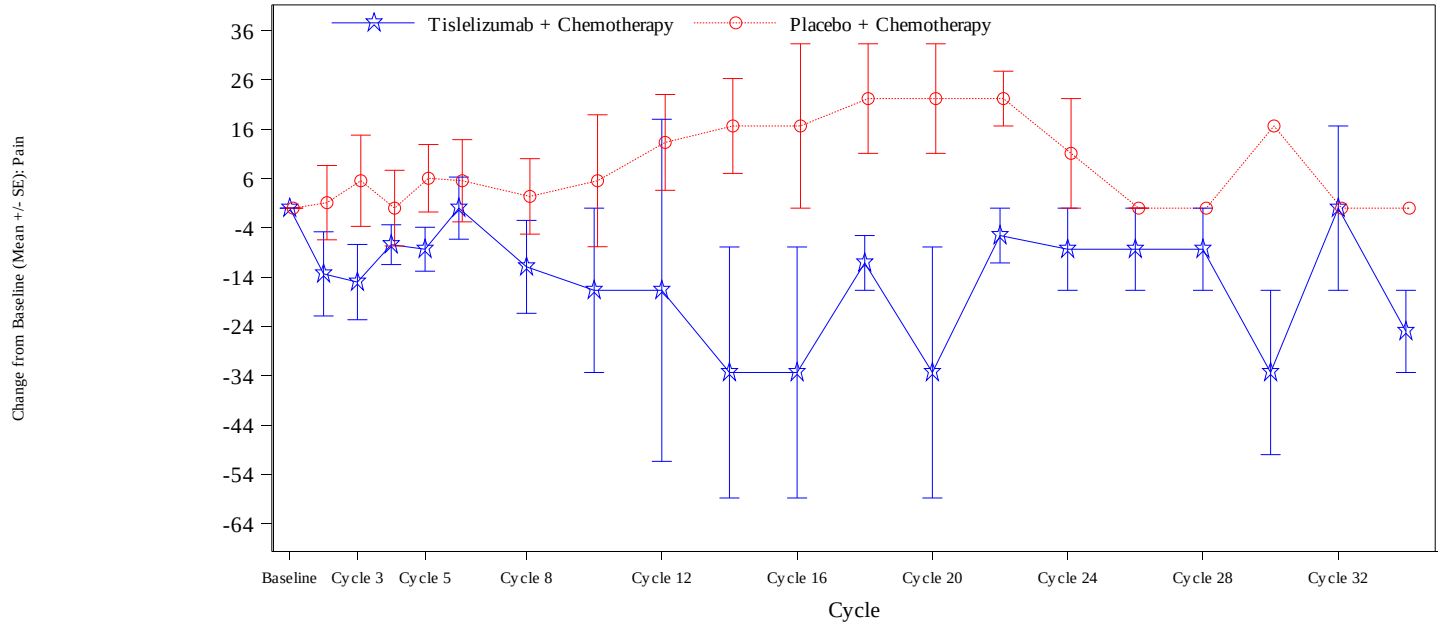

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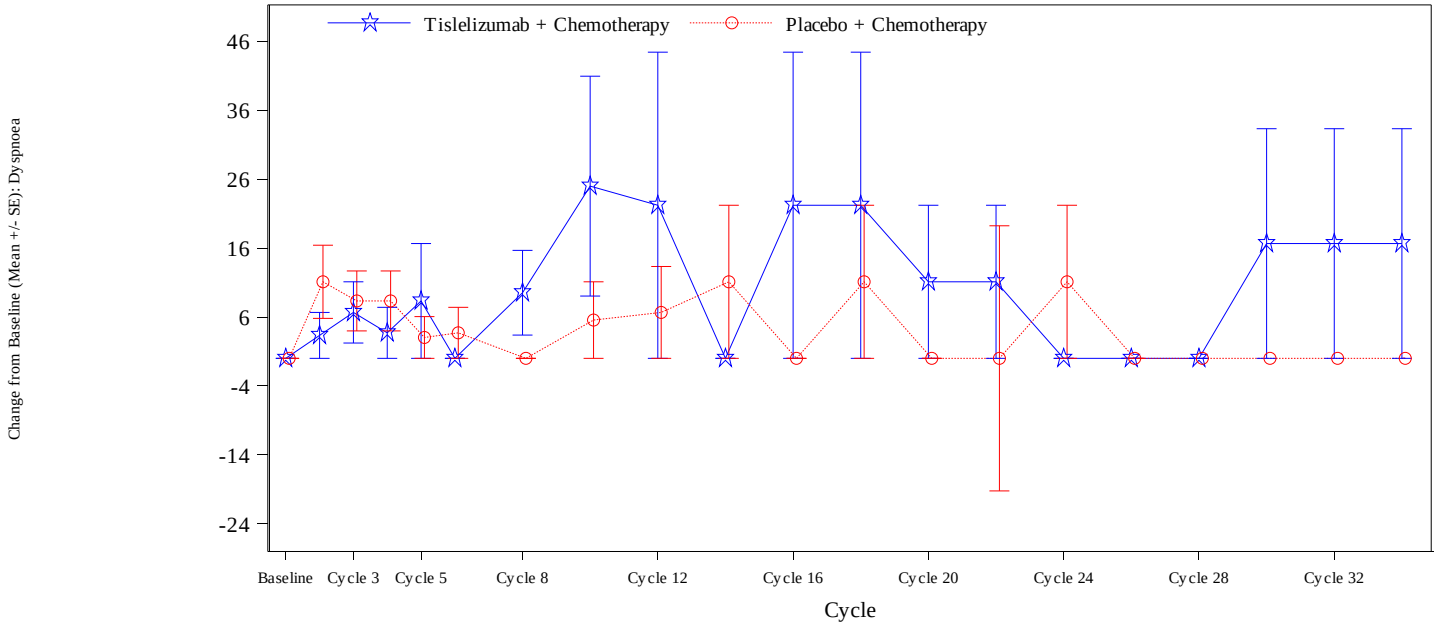

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Figure 14.2.7.1:
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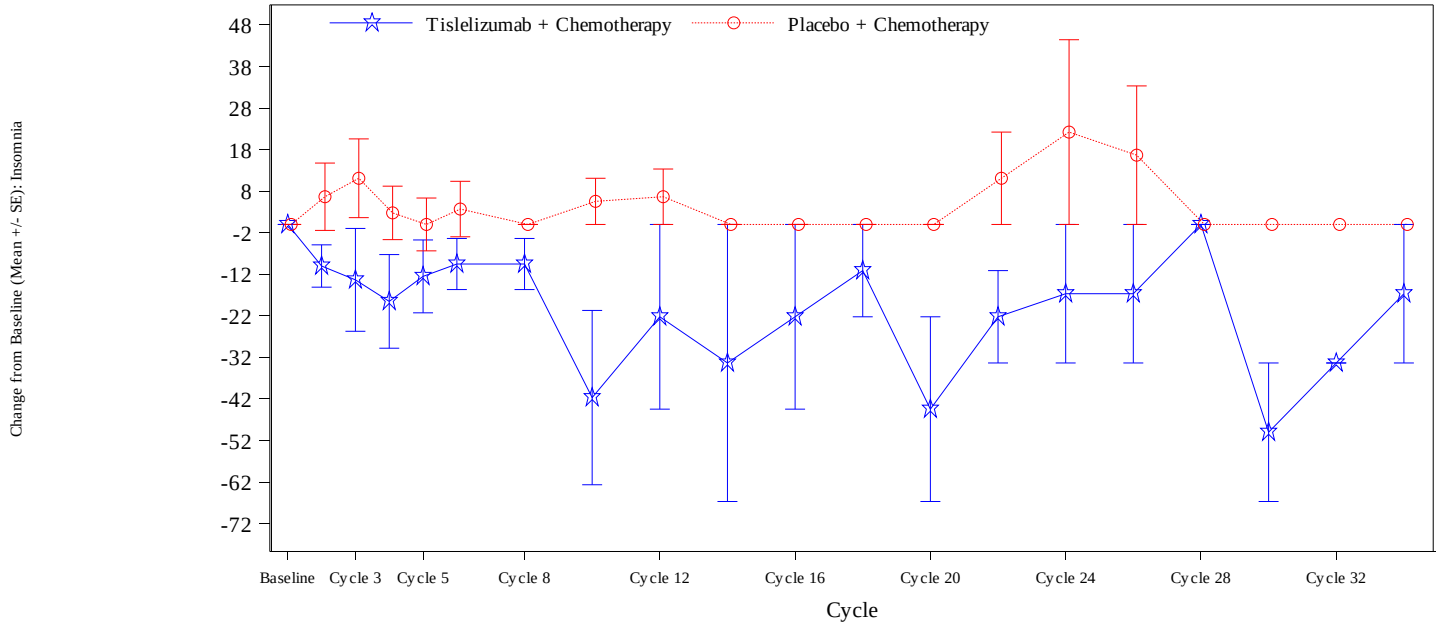

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Figure 14.2.7.1:
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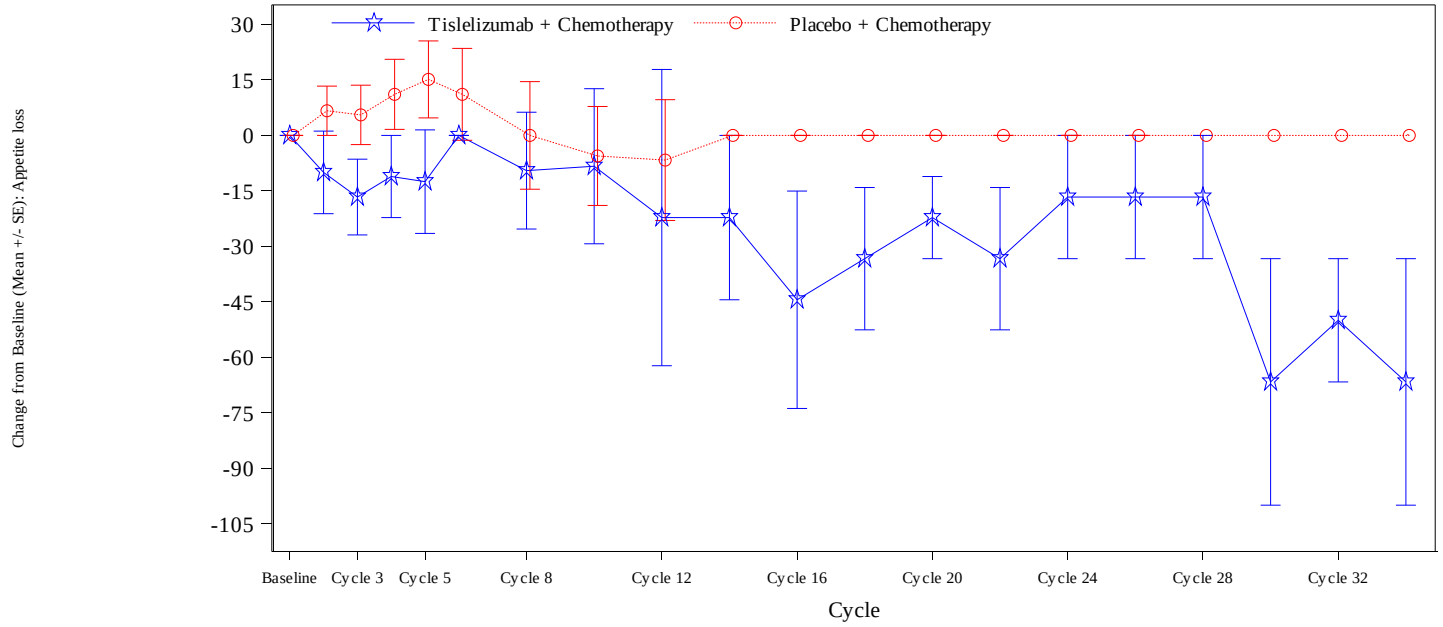
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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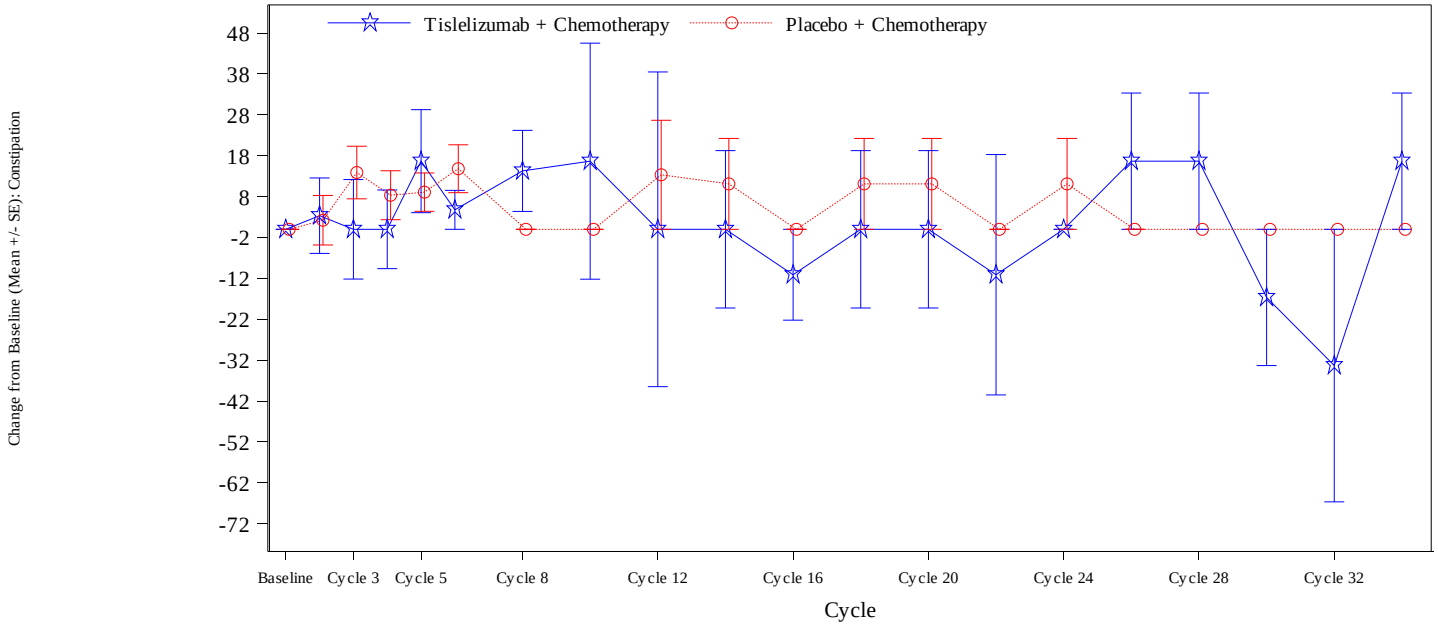

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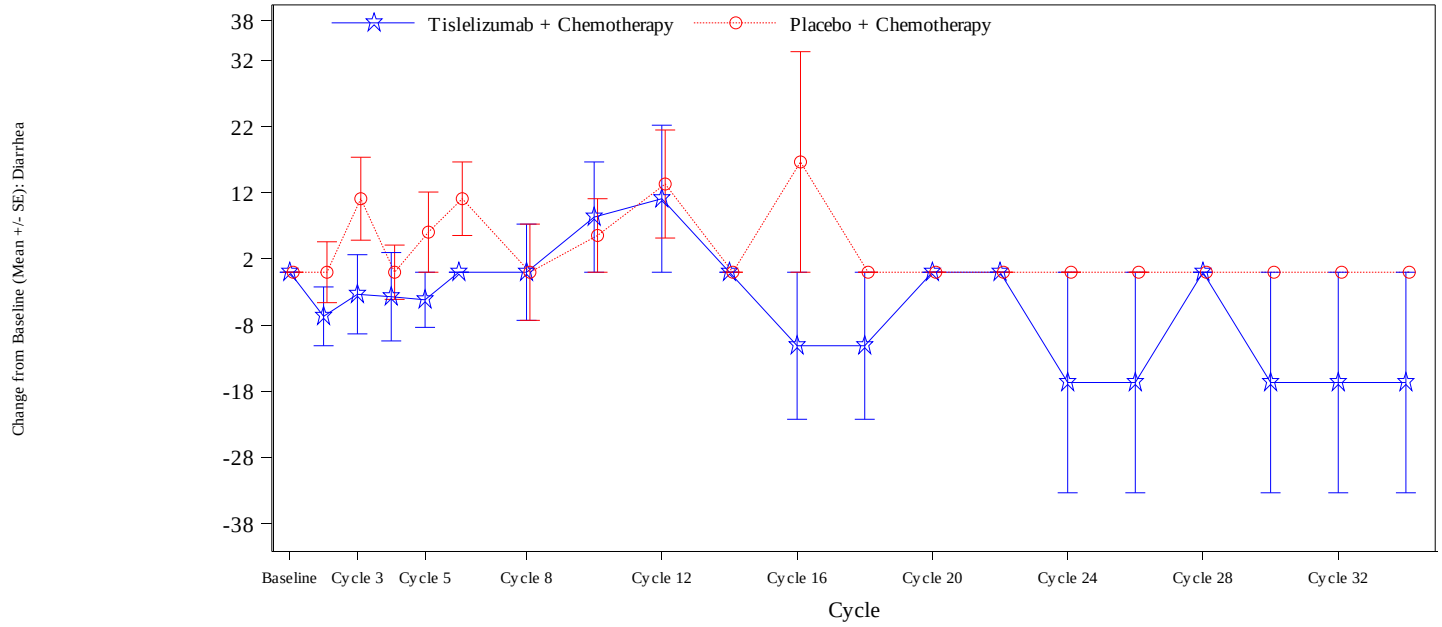

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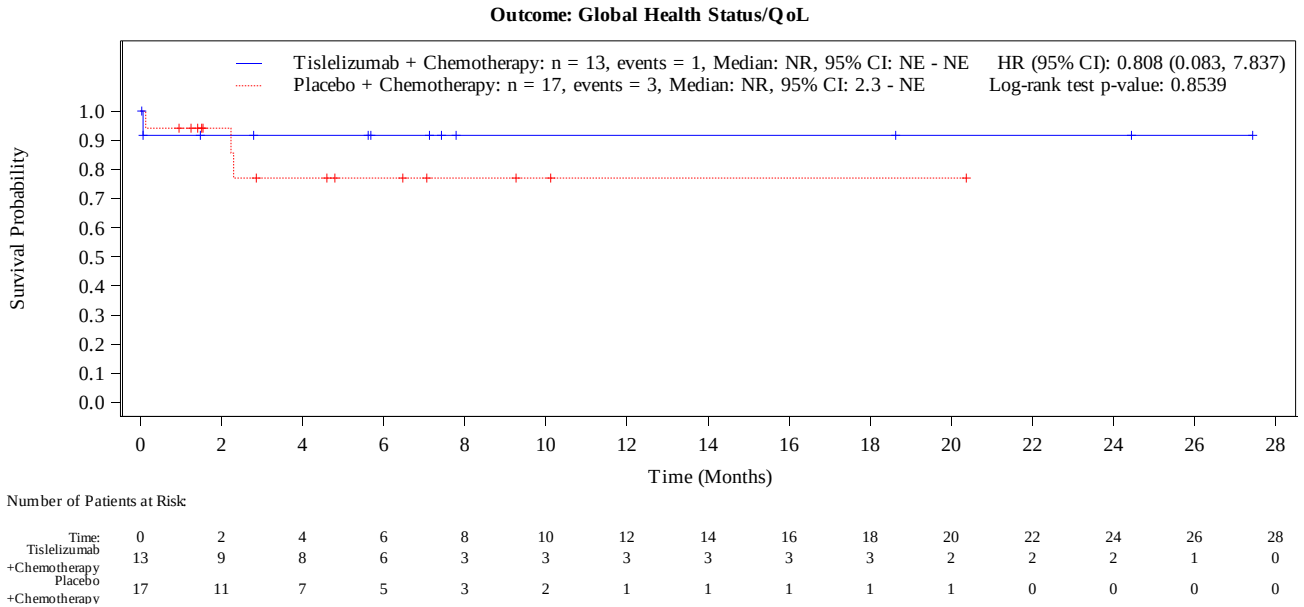
Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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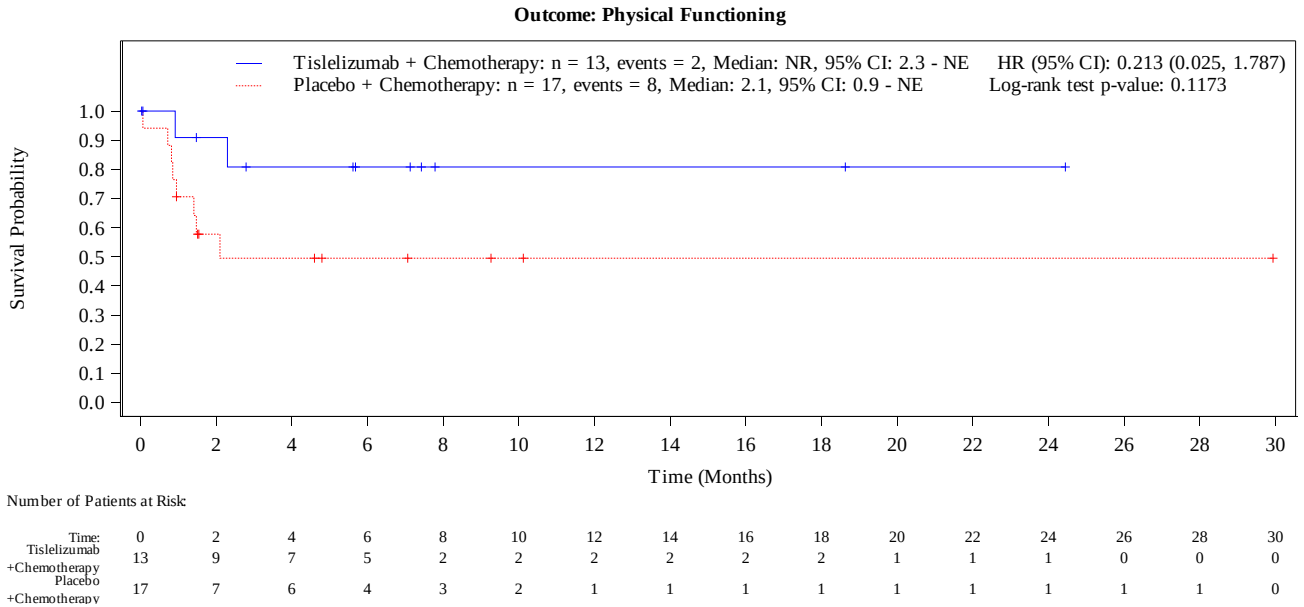
Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

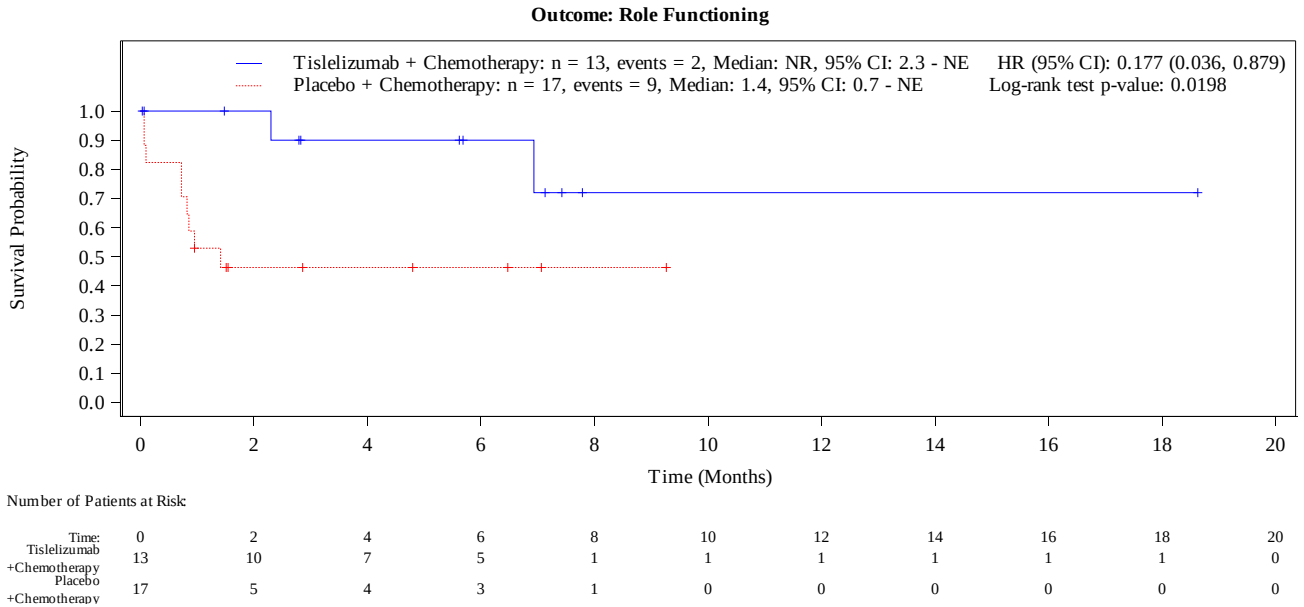

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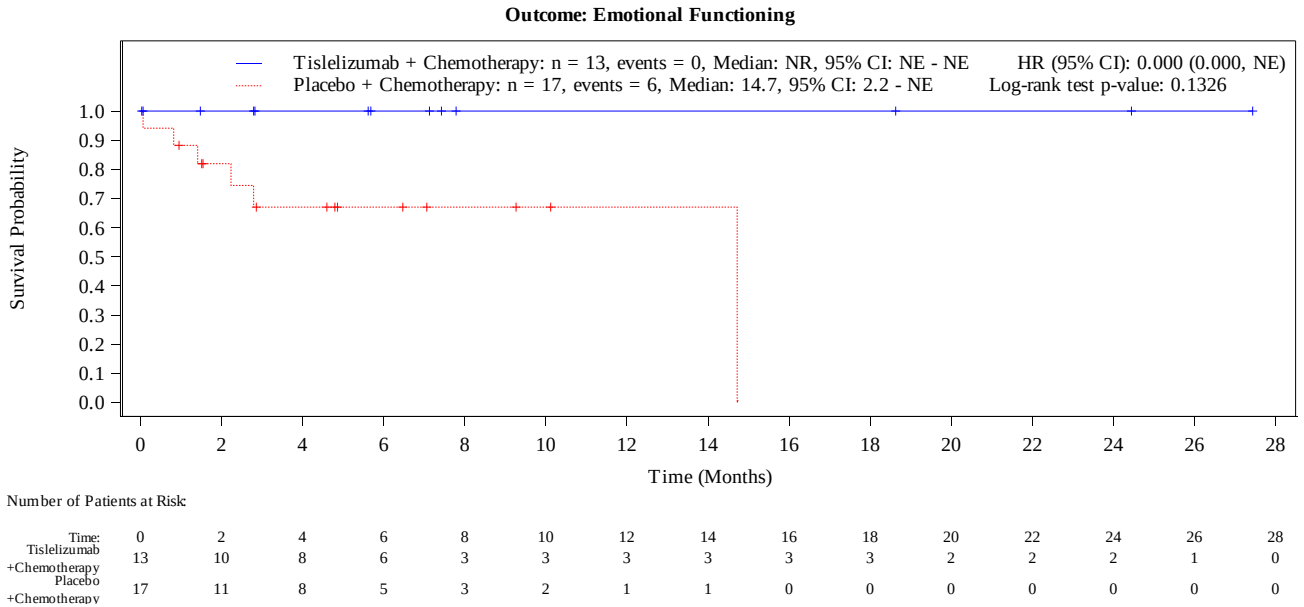
Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: NE = not estimable; NR = not reached
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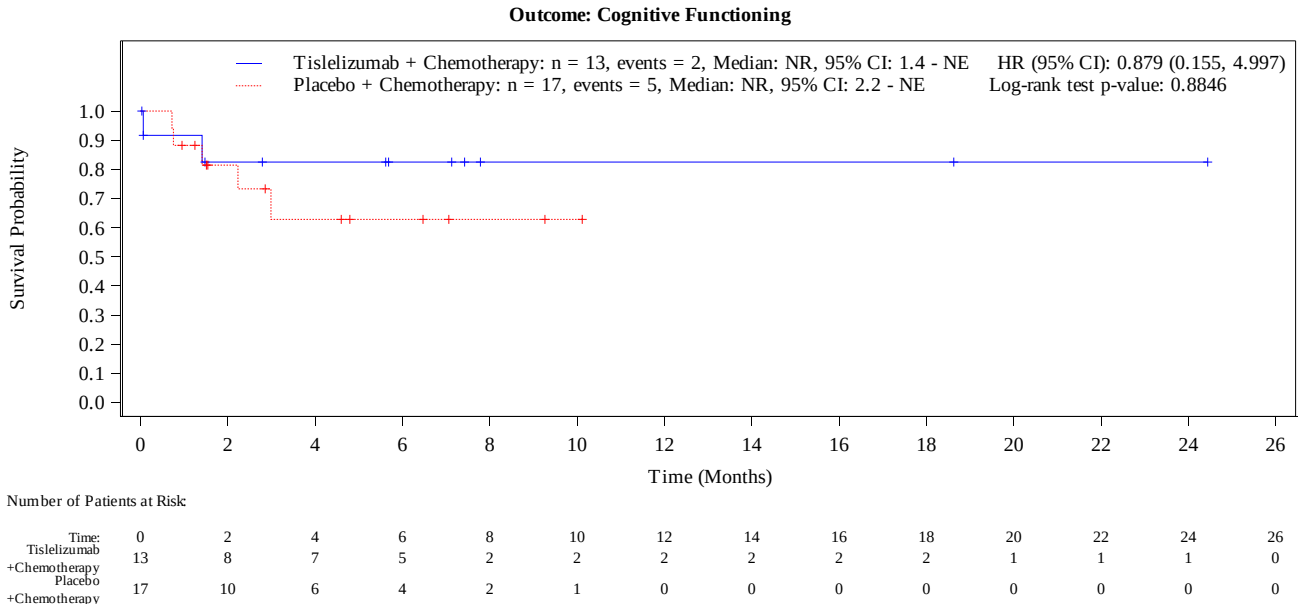
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-ia.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

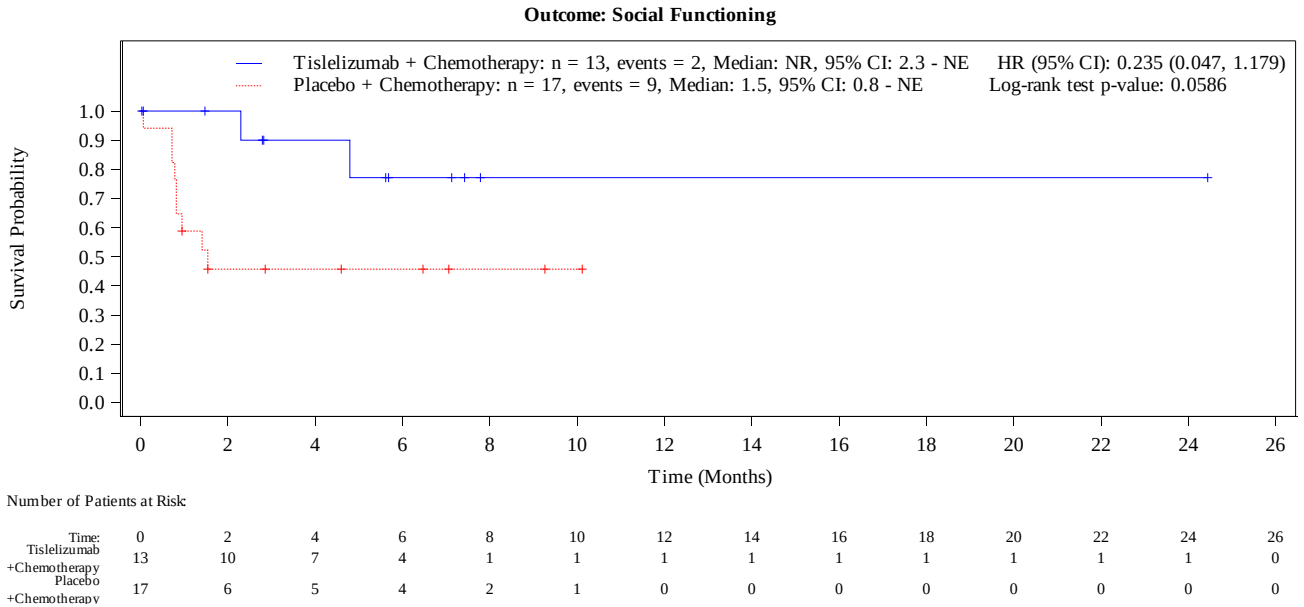

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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

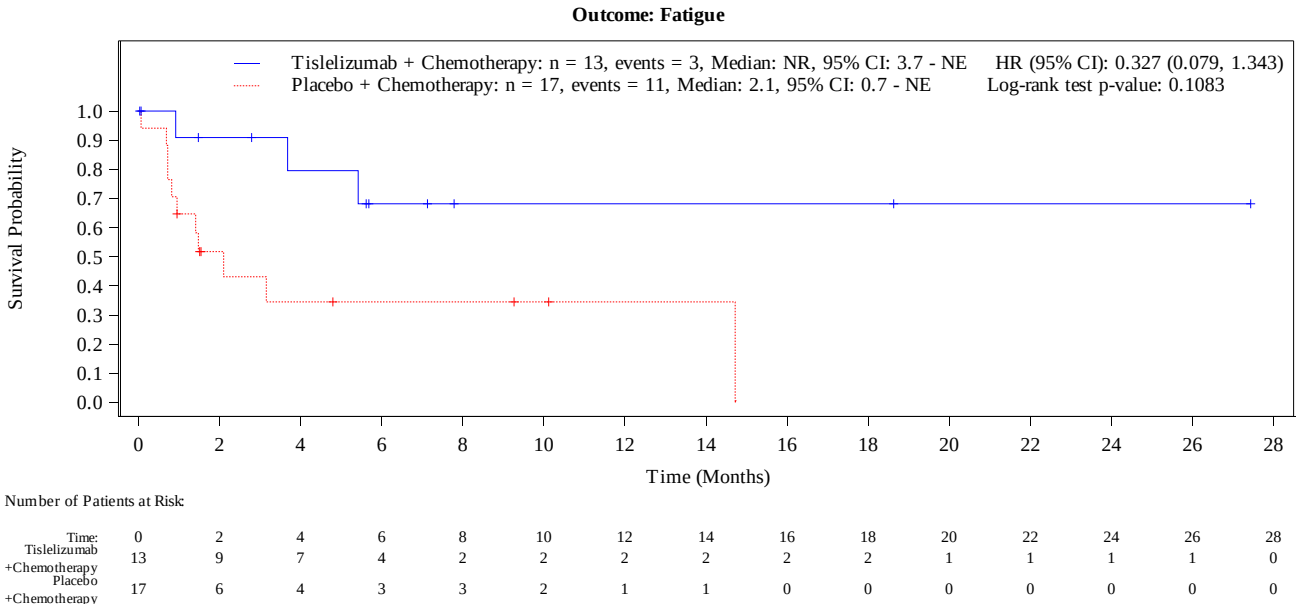

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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

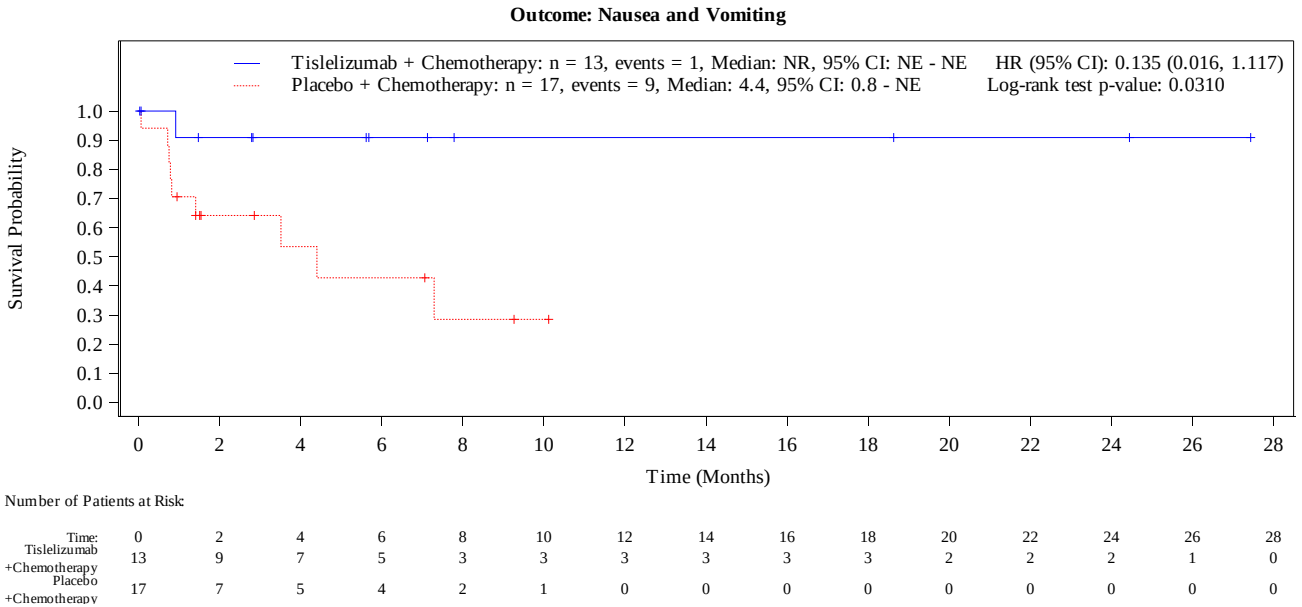

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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

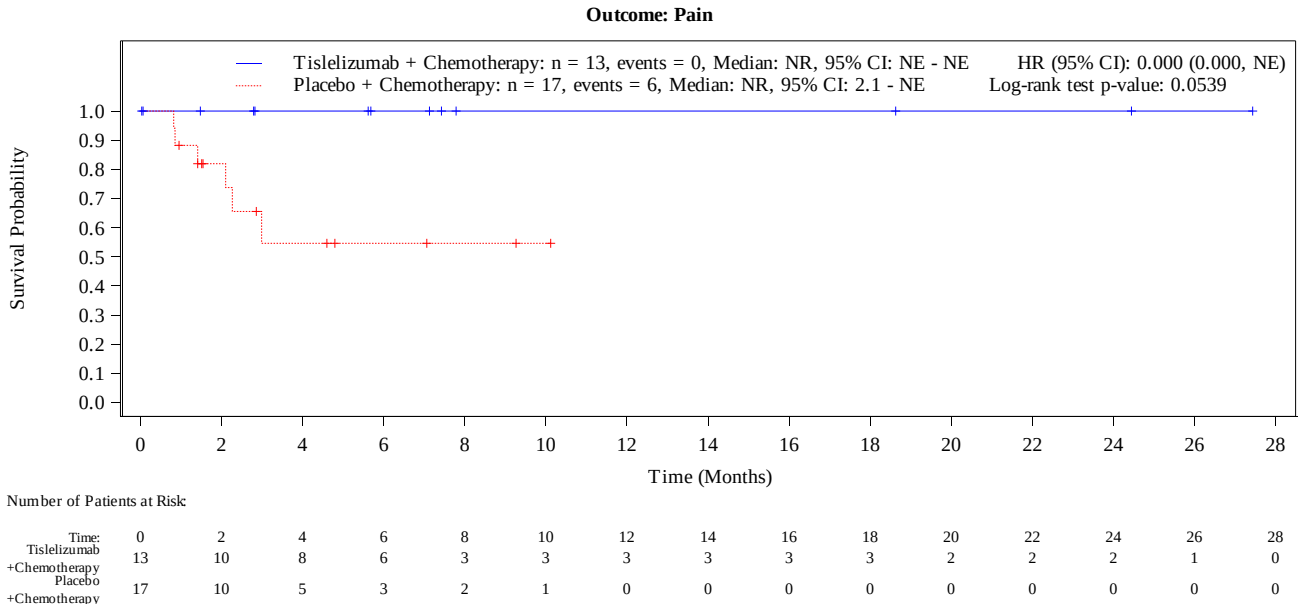

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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

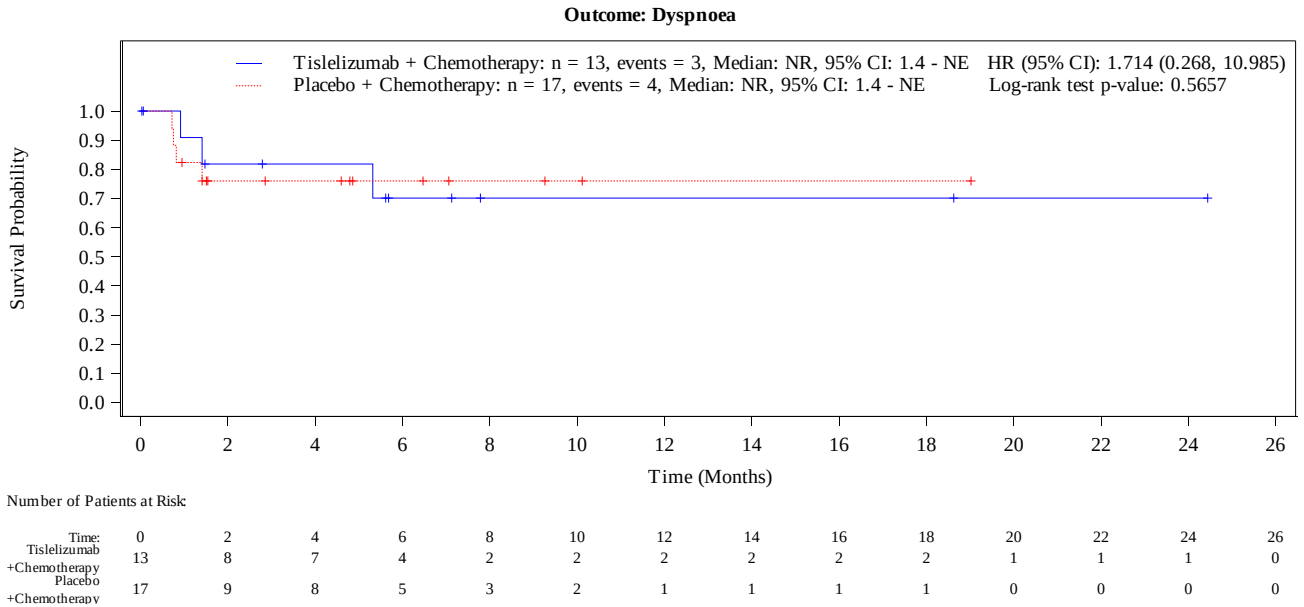

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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

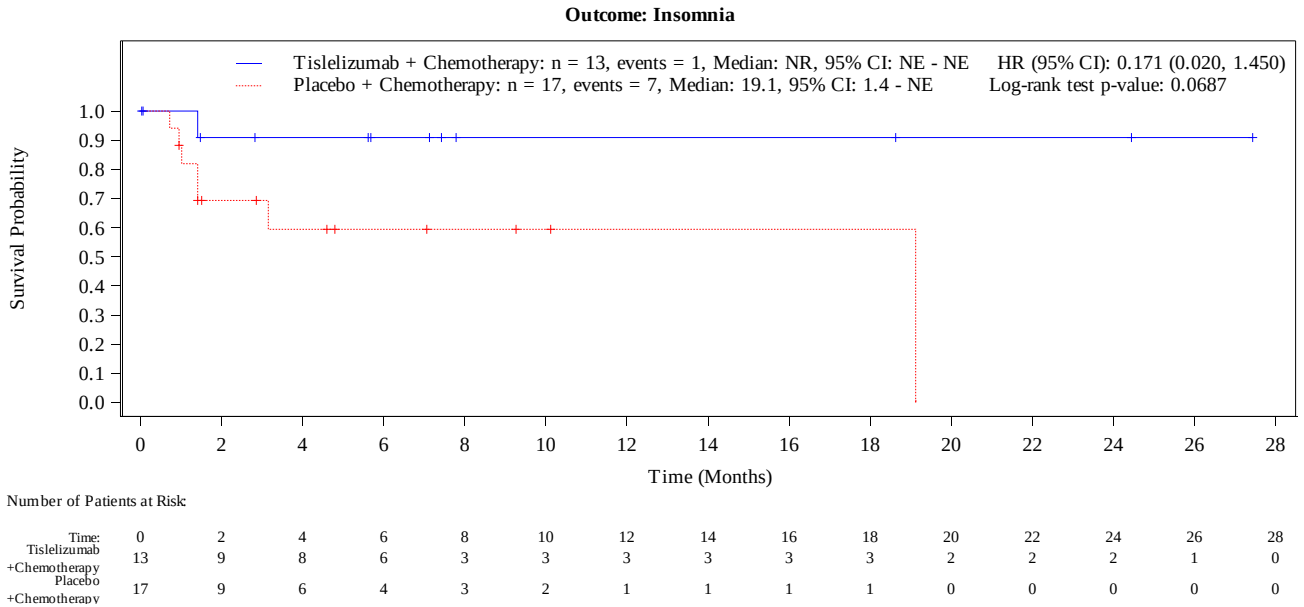

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Figure 14.2.7.1.2:
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ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

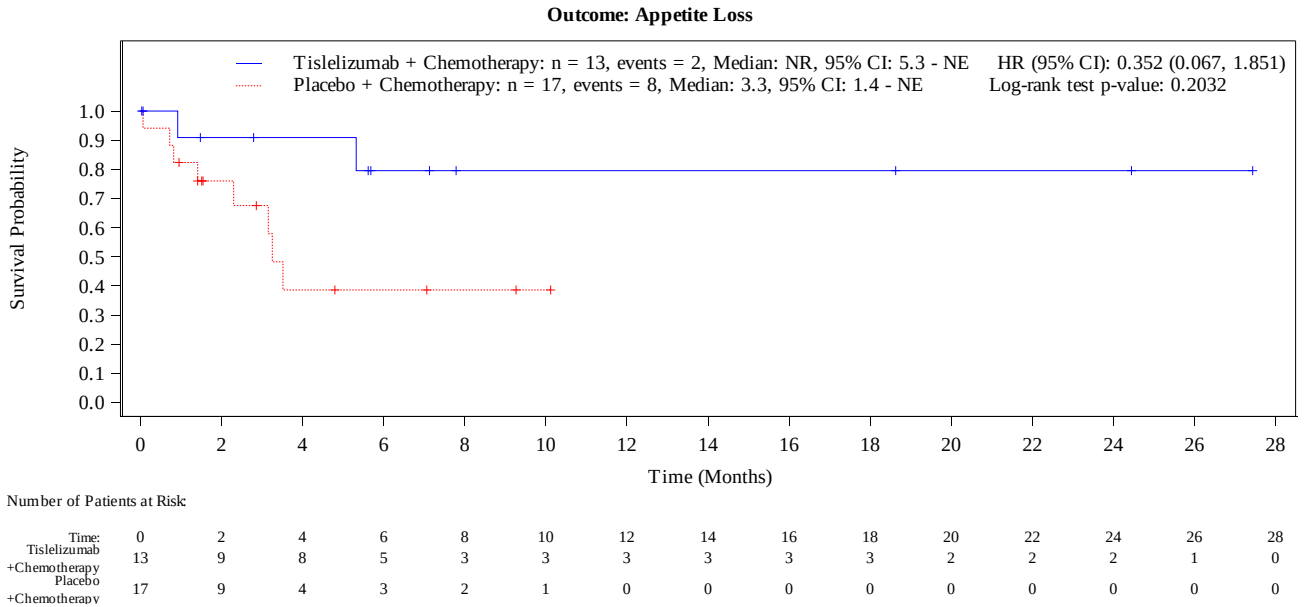

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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

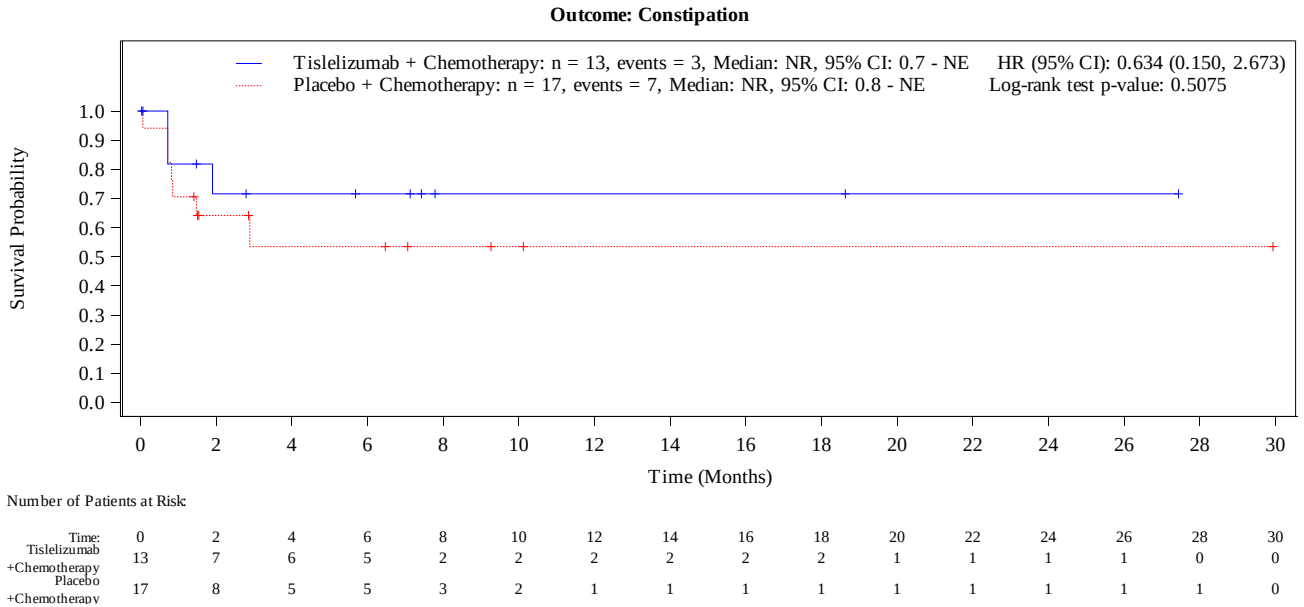

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Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

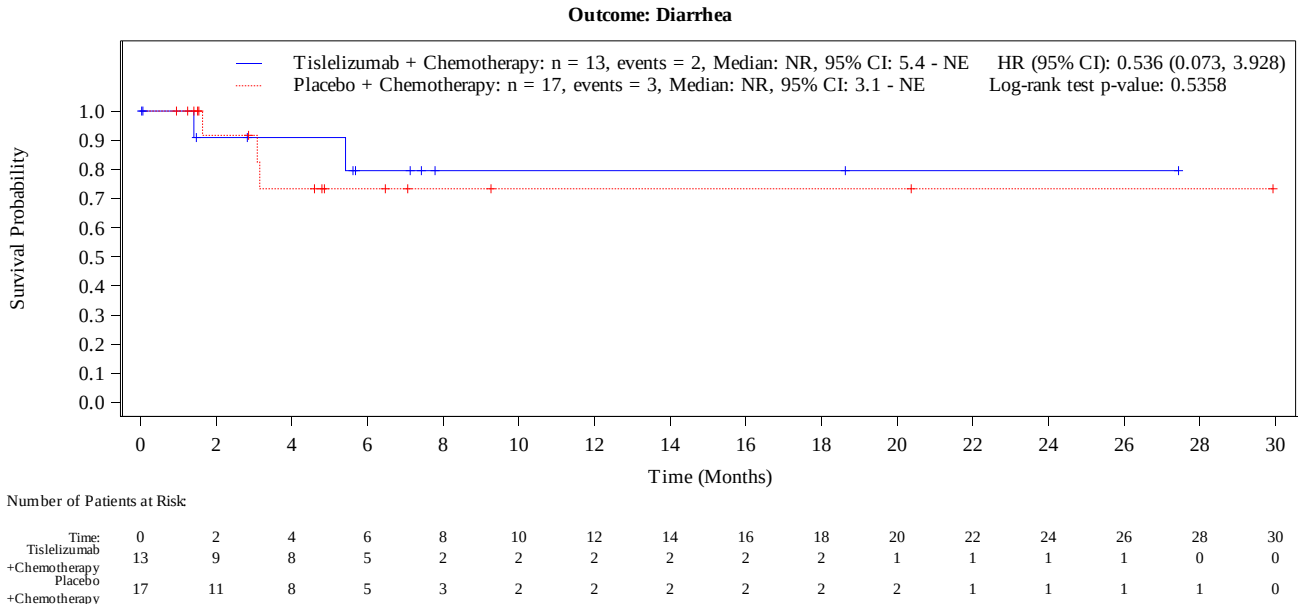

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	6 (85.7)	--	--	--
No	9	0 (0.0)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	7 (63.6)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	3 (37.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	6 (75.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	7 (63.6)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	6 (60.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	7 (100.0)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	5 (83.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	2 (18.2)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-ia.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

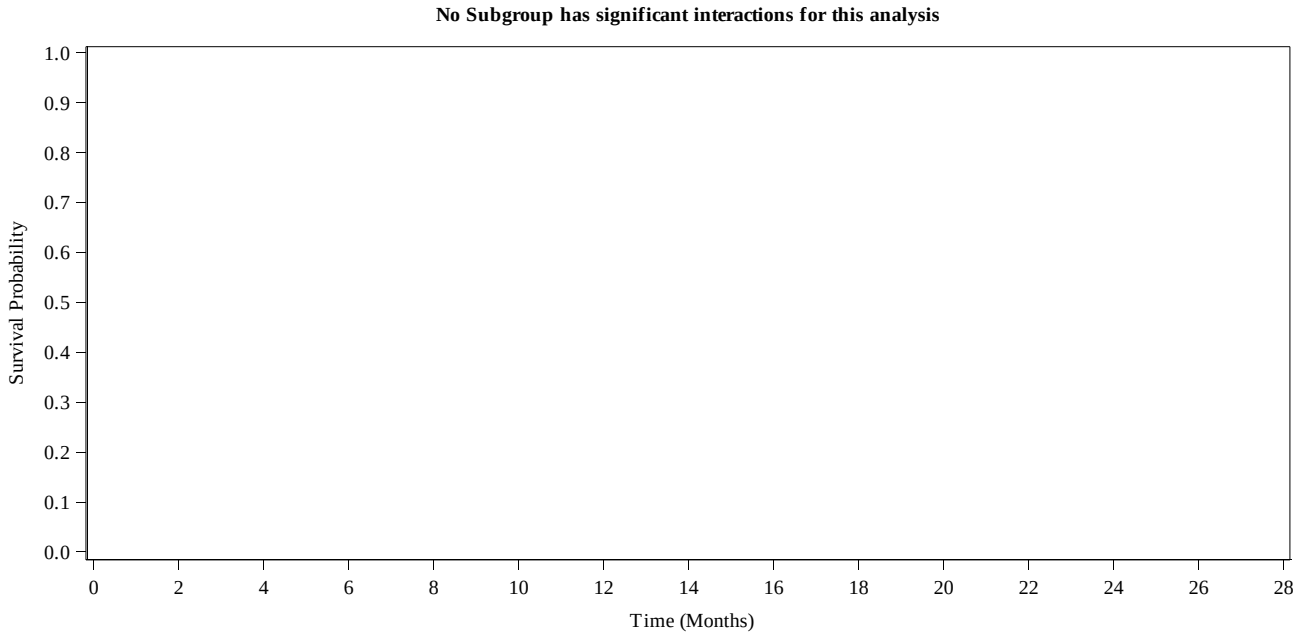
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-ia.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-1-2-s-km-tteqs-subgrp-c30-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	53.7 (36.03)		58.2 (33.22)	
	Median	61.1		66.7	
	Q1, Q3	22.2, 83.3		33.3, 77.8	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	63.3 (40.25)	4.4 (19.74)	60.0 (34.32)	0.0 (34.12)
	Median	77.8	5.6	66.7	0.0
	Q1, Q3	11.1, 100.0	0.0, 11.1	33.3, 88.9	-33.3, 11.1
	Min, Max	0, 100	-33, 44	0, 100	-56, 78
Cycle 3	n	10	10	11	11
	Mean (SD)	56.7 (36.83)	-2.2 (15.54)	44.4 (39.13)	-18.2 (22.92)
	Median	66.7	0.0	55.6	-11.1
	Q1, Q3	22.2, 88.9	0.0, 0.0	0.0, 88.9	-33.3, 0.0
	Min, Max	0, 100	-33, 22	0, 100	-56, 11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	75.3 (35.91)	19.8 (33.69)	37.0 (37.41)	-20.4 (23.61)
	Median	88.9	11.1	38.9	-11.1
	Q1, Q3	66.7, 100.0	0.0, 22.2	0.0, 66.7	-33.3, 0.0
	Min, Max	0, 100	-22, 89	0, 100	-67, 0
Cycle 5	n	8	8	11	11
	Mean (SD)	62.5 (40.69)	9.7 (22.57)	49.5 (38.61)	-13.1 (26.68)
	Median	83.3	11.1	44.4	-11.1
	Q1, Q3	22.2, 94.4	0.0, 22.2	11.1, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 44	0, 100	-67, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	66.7 (40.57)	14.3 (19.99)	54.3 (40.61)	-6.2 (31.48)
	Median	77.8	11.1	66.7	0.0
	Q1, Q3	22.2, 100.0	0.0, 22.2	11.1, 77.8	-11.1, 0.0
	Min, Max	0, 100	0, 56	0, 100	-67, 44

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	65.1 (46.00)	14.3 (46.13)	39.7 (41.00)	-15.9 (23.88)
	Median	88.9	0.0	33.3	-11.1
	Q1, Q3	0.0, 100.0	0.0, 55.6	0.0, 88.9	-22.2, 0.0
	Min, Max	0, 100	-56, 89	0, 100	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	47.2 (44.79)	-8.3 (33.18)	48.1 (45.36)	-7.4 (41.38)
	Median	44.4	0.0	44.4	0.0
	Q1, Q3	11.1, 83.3	-27.8, 11.1	0.0, 100.0	-44.4, 22.2
	Min, Max	0, 100	-56, 22	0, 100	-67, 44
Cycle 12	n	3	3	5	5
	Mean (SD)	7.4 (12.83)	-44.4 (61.86)	60.0 (43.46)	-6.7 (44.17)
	Median	0.0	-55.6	66.7	0.0
	Q1, Q3	0.0, 22.2	-100.0, 22.2	33.3, 100.0	-33.3, 22.2
	Min, Max	0, 22	-100, 22	0, 100	-67, 44

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	63.0 (54.81)	11.1 (98.76)	63.0 (54.81)	-25.9 (35.72)
	Median	88.9	44.4	88.9	-11.1
	Q1, Q3	0.0, 100.0	-100.0, 88.9	0.0, 100.0	-66.7, 0.0
	Min, Max	0, 100	-100, 89	0, 100	-67, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	37.0 (54.81)	-14.8 (75.63)	33.3 (47.14)	-22.2 (15.71)
	Median	11.1	11.1	33.3	-22.2
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-33.3, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-33, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	40.7 (44.91)	-11.1 (94.93)	22.2 (38.49)	-37.0 (27.96)
	Median	33.3	-22.2	0.0	-33.3
	Q1, Q3	0.0, 88.9	-100.0, 88.9	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 89	-100, 89	0, 67	-67, -11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	-18.5 (73.98)	22.2 (38.49)	-37.0 (27.96)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-67, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-40.7 (52.51)	40.7 (39.02)	-18.5 (50.10)
	Median	0.0	-22.2	44.4	-22.2
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 77.8	-66.7, 33.3
	Min, Max	0, 33	-100, 0	0, 78	-67, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-33.3 (94.28)	22.2 (38.49)	-37.0 (27.96)
	Median	16.7	-33.3	0.0	-33.3
	Q1, Q3	0.0, 33.3	-100.0, 33.3	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 33	-100, 33	0, 67	-67, -11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	5.6 (7.86)	-33.3 (31.43)
	Median	0.0	-50.0	5.6	-33.3
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 11.1	-55.6, -11.1
	Min, Max	0, 0	-100, 0	0, 11	-56, -11
Cycle 28	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-44.4 (78.57)	0.0 (NE)	-11.1 (NE)
	Median	5.6	-44.4	0.0	-11.1
	Q1, Q3	0.0, 11.1	-100.0, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-100, 11	0, 0	-11, -11
Cycle 30	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-22.2 (47.14)	0.0 (NE)	-11.1 (NE)
	Median	5.6	-22.2	0.0	-11.1
	Q1, Q3	0.0, 11.1	-55.6, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-56, 11	0, 0	-11, -11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-22.2 (47.14)	0.0 (NE)	-11.1 (NE)
	Median	5.6	-22.2	0.0	-11.1
	Q1, Q3	0.0, 11.1	-55.6, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-56, 11	0, 0	-11, -11
Cycle 34	n	2	2	1	1
	Mean (SD)	44.4 (62.85)	16.7 (102.14)	0.0 (NE)	-11.1 (NE)
	Median	44.4	16.7	0.0	-11.1
	Q1, Q3	0.0, 88.9	-55.6, 88.9	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 89	-56, 89	0, 0	-11, -11
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 42	n	0	0	1	1
	Mean (SD)			22.2 (NE)	11.1 (NE)
	Median			22.2	11.1
	Q1, Q3			22.2, 22.2	11.1, 11.1
	Min, Max			22, 22	11, 11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			22.2 (NE)	11.1 (NE)
	Median			22.2	11.1
	Q1, Q3			22.2, 22.2	11.1, 11.1
	Min, Max			22, 22	11, 11
End of Treatment	n	9	9	14	14
	Mean (SD)	53.1 (41.86)	4.9 (17.67)	48.4 (34.76)	-9.5 (27.51)
	Median	66.7	0.0	55.6	0.0
	Q1, Q3	0.0, 88.9	0.0, 0.0	22.2, 66.7	-22.2, 11.1
	Min, Max	0, 100	-11, 44	0, 100	-56, 44

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	75.9 (38.73)	22.2 (31.43)	79.7 (21.60)	21.6 (23.40)
	Median	94.4	16.7	88.9	22.2
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	11.1, 33.3
	Min, Max	0, 100	-11, 100	33, 100	-22, 78

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	27.1 (30.18)		29.4 (24.32)	
	Median	25.0		16.7	
	Q1, Q3	0.0, 33.3		8.3, 41.7	
	Min, Max	0, 100		0, 75	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.0 (17.92)	-10.8 (32.64)	35.6 (26.81)	6.1 (16.20)
	Median	8.3	0.0	33.3	0.0
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 41.7	-8.3, 16.7
	Min, Max	0, 50	-100, 17	0, 100	-17, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	15.0 (16.57)	-10.8 (31.93)	32.6 (26.99)	-0.8 (18.80)
	Median	12.5	0.0	25.0	0.0
	Q1, Q3	0.0, 25.0	0.0, 0.0	16.7, 50.0	-8.3, 16.7
	Min, Max	0, 42	-100, 8	0, 92	-42, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (12.11)	-15.7 (33.71)	34.7 (25.58)	4.2 (18.97)
	Median	8.3	0.0	25.0	0.0
	Q1, Q3	0.0, 8.3	-16.7, 0.0	16.7, 58.3	-4.2, 12.5
	Min, Max	0, 33	-100, 8	0, 75	-25, 50
Cycle 5	n	8	8	11	11
	Mean (SD)	10.4 (10.68)	-14.6 (32.35)	31.8 (29.06)	5.3 (26.42)
	Median	8.3	0.0	25.0	8.3
	Q1, Q3	0.0, 20.8	-16.7, 0.0	0.0, 66.7	-16.7, 25.0
	Min, Max	0, 25	-92, 8	0, 67	-42, 50
Cycle 6	n	7	7	9	9
	Mean (SD)	13.1 (16.57)	-1.2 (7.50)	25.9 (23.73)	0.0 (22.44)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	8.3, 33.3	-8.3, 16.7
	Min, Max	0, 33	-17, 8	0, 67	-42, 25

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	-17.9 (37.40)	21.4 (24.47)	3.6 (27.58)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 50.0	-16.7, 25.0
	Min, Max	0, 33	-100, 8	0, 58	-42, 42
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (15.96)	-18.8 (43.23)	19.4 (36.77)	0.0 (34.56)
	Median	25.0	0.0	0.0	-8.3
	Q1, Q3	8.3, 33.3	-41.7, 4.2	0.0, 25.0	-16.7, 16.7
	Min, Max	0, 33	-83, 8	0, 92	-42, 58
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-33.3 (57.74)	16.7 (28.26)	-6.7 (27.26)
	Median	0.0	0.0	8.3	-8.3
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 8.3	-16.7, 0.0
	Min, Max	0, 33	-100, 0	0, 67	-42, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	2.8 (4.81)	-41.7 (46.40)	16.7 (22.05)	-5.6 (12.73)
	Median	0.0	-33.3	8.3	-8.3
	Q1, Q3	0.0, 8.3	-91.7, 0.0	0.0, 41.7	-16.7, 8.3
	Min, Max	0, 8	-92, 0	0, 42	-17, 8
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-38.9 (41.94)	20.8 (29.46)	0.0 (11.79)
	Median	0.0	-33.3	20.8	0.0
	Q1, Q3	0.0, 16.7	-83.3, 0.0	0.0, 41.7	-8.3, 8.3
	Min, Max	0, 17	-83, 0	0, 42	-8, 8
Cycle 18	n	3	3	3	3
	Mean (SD)	19.4 (17.35)	-25.0 (43.30)	16.7 (16.67)	-2.8 (12.73)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-75.0, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-75, 0	0, 33	-17, 8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	16.7 (16.67)	-2.8 (12.73)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-67, 0	0, 33	-17, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	22.2 (19.25)	2.8 (20.97)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 25.0
	Min, Max	0, 33	-67, 0	0, 33	-17, 25
Cycle 24	n	2	2	3	3
	Mean (SD)	8.3 (11.79)	-8.3 (11.79)	19.4 (12.73)	0.0 (8.33)
	Median	8.3	-8.3	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	8.3, 33.3	-8.3, 8.3
	Min, Max	0, 17	-17, 0	8, 33	-8, 8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	12.5 (17.68)	-4.2 (5.89)	16.7 (0.00)	4.2 (5.89)
	Median	12.5	-4.2	16.7	4.2
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 16.7	0.0, 8.3
	Min, Max	0, 25	-8, 0	17, 17	0, 8
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	25.0 (NE)	16.7 (NE)
	Median	16.7	0.0	25.0	16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	25.0, 25.0	16.7, 16.7
	Min, Max	0, 33	0, 0	25, 25	17, 17
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-50.0 (70.71)	0.0 (NE)	-8.3 (NE)
	Median	16.7	-50.0	0.0	-8.3
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 0.0	-8.3, -8.3
	Min, Max	0, 33	-100, 0	0, 0	-8, -8

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	29.2 (5.89)	-37.5 (53.03)	8.3 (NE)	0.0 (NE)
	Median	29.2	-37.5	8.3	0.0
	Q1, Q3	25.0, 33.3	-75.0, 0.0	8.3, 8.3	0.0, 0.0
	Min, Max	25, 33	-75, 0	8, 8	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	12.5 (17.68)	-54.2 (29.46)	16.7 (NE)	8.3 (NE)
	Median	12.5	-54.2	16.7	8.3
	Q1, Q3	0.0, 25.0	-75.0, -33.3	16.7, 16.7	8.3, 8.3
	Min, Max	0, 25	-75, -33	17, 17	8, 8
Cycle 36	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			16.7 (NE)	8.3 (NE)
	Median			16.7	8.3
	Q1, Q3			16.7, 16.7	8.3, 8.3
	Min, Max			17, 17	8, 8
Cycle 42	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	25.0 (NE)
	Median			33.3	25.0
	Q1, Q3			33.3, 33.3	25.0, 25.0
	Min, Max			33, 33	25, 25
End of Treatment	n	9	9	14	14
	Mean (SD)	16.7 (15.59)	-0.9 (16.37)	41.7 (28.68)	10.1 (26.79)
	Median	16.7	0.0	41.7	0.0
	Q1, Q3	0.0, 25.0	-8.3, 8.3	16.7, 58.3	0.0, 33.3
	Min, Max	0, 42	-33, 17	0, 83	-42, 58

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	31.9 (26.07)	4.9 (24.99)	56.4 (25.94)	27.0 (20.10)
	Median	33.3	8.3	50.0	25.0
	Q1, Q3	8.3, 50.0	0.0, 16.7	41.7, 66.7	16.7, 41.7
	Min, Max	0, 83	-67, 33	17, 100	-8, 58

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	4.2 (10.36)		12.7 (20.01)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 16.7	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (10.54)	14.4 (17.67)	3.3 (9.34)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 50	-17, 17
Cycle 3	n	10	10	11	11
	Mean (SD)	5.0 (11.25)	0.0 (7.86)	18.2 (17.41)	4.5 (16.82)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 17	0, 50	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	0.0 (0.00)	-5.6 (11.79)	13.9 (18.58)	1.4 (16.60)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 8.3
	Min, Max	0, 0	-33, 0	0, 50	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	2.1 (5.89)	-4.2 (7.72)	13.6 (17.98)	1.5 (17.41)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-8.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	0, 50	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	16.7 (16.67)	1.9 (22.74)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 50	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (0.00)	9.5 (16.27)	0.0 (21.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 33	0, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (20.97)	8.3 (9.62)	5.6 (13.61)	-5.6 (17.21)
	Median	16.7	8.3	0.0	0.0
	Q1, Q3	8.3, 33.3	0.0, 16.7	0.0, 0.0	-16.7, 0.0
	Min, Max	0, 50	0, 17	0, 33	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	6.7 (9.13)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	25.0 (11.79)	8.3 (11.79)
	Median	0.0	-16.7	25.0	8.3
	Q1, Q3	0.0, 16.7	-16.7, 0.0	16.7, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	17, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	22.2 (19.25)	11.1 (9.62)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 33	0, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	5.6 (9.62)	-5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	-16.7, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (9.62)	-5.6 (9.62)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 17	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (0.00)	-8.3 (11.79)
	Median	0.0	-16.7	0.0	-8.3
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	-16.7, 0.0
	Min, Max	0, 0	-33, 0	0, 0	-17, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	-16.7 (NE)
	Median	0.0	-16.7	0.0	-16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	0, 0	-33, 0	0, 0	-17, -17
Cycle 30	n	2	2	1	1
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	0.0 (NE)	-16.7 (NE)
	Median	25.0	0.0	0.0	-16.7
	Q1, Q3	16.7, 33.3	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	17, 33	0, 0	0, 0	-17, -17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	0.0 (NE)	-16.7 (NE)
	Median	25.0	0.0	0.0	-16.7
	Q1, Q3	16.7, 33.3	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	17, 33	0, 0	0, 0	-17, -17
Cycle 34	n	2	2	1	1
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	16.7 (NE)	0.0 (NE)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	16.7, 33.3	0.0, 0.0	16.7, 16.7	0.0, 0.0
	Min, Max	17, 33	0, 0	17, 17	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-16.7 (NE)
	Median			0.0	-16.7
	Q1, Q3			0.0, 0.0	-16.7, -16.7
	Min, Max			0, 0	-17, -17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			16.7 (NE)	0.0 (NE)
	Median			16.7	0.0
	Q1, Q3			16.7, 16.7	0.0, 0.0
	Min, Max			17, 17	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	5.6 (8.33)	1.9 (15.47)	15.5 (16.62)	2.4 (20.52)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 17	-33, 17	0, 33	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	12.5 (16.09)	8.3 (11.24)	28.4 (18.41)	15.7 (16.11)
	Median	8.3	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 16.7	16.7, 50.0	0.0, 33.3
	Min, Max	0, 50	0, 33	0, 50	-17, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	12.0 (18.02)		22.9 (20.21)	
	Median	0.0		22.2	
	Q1, Q3	0.0, 22.2		11.1, 33.3	
	Min, Max	0, 56		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.5 (21.61)	-1.5 (15.64)
	Median	0.0	0.0	22.2	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 22	-33, 11	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.2 (23.55)	-4.0 (15.13)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 0.0
	Min, Max	0, 22	-33, 11	0, 67	-33, 22

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (7.86)	-9.9 (15.16)	14.8 (18.55)	-8.3 (15.08)
	Median	0.0	0.0	5.6	-5.6
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 27.8	-16.7, 0.0
	Min, Max	0, 22	-33, 0	0, 56	-33, 11
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	-8.3 (12.94)	17.2 (25.99)	-3.0 (20.54)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 0	-33, 0	0, 89	-33, 44
Cycle 6	n	7	7	9	9
	Mean (SD)	1.6 (4.20)	-3.2 (10.57)	16.0 (21.60)	-2.5 (17.37)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-11.1, 0.0	0.0, 11.1	-11.1, 11.1
	Min, Max	0, 11	-22, 11	0, 67	-33, 22

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.74)	-4.8 (10.84)	7.9 (12.36)	-4.8 (14.14)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (10.64)	-5.6 (14.34)	7.4 (13.46)	-5.6 (15.32)
	Median	5.6	-5.6	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 5.6	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (11.11)	-7.4 (12.83)	6.7 (14.91)	-8.9 (14.49)
	Median	11.1	0.0	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, 0.0	0.0, 0.0	-11.1, 0.0
	Min, Max	0, 22	-22, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	14.8 (16.97)	0.0 (11.11)
	Median	0.0	-22.2	11.1	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 0	-33, 0	0, 33	-11, 11
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-22.2	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	3.7 (6.42)	-14.8 (12.83)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 11	-22, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	3.7 (27.96)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-22.2, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-22, 33	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	14.8 (16.97)	3.7 (6.42)
	Median	0.0	-11.1	11.1	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 11.1
	Min, Max	0, 0	-22, 0	0, 33	0, 11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	0.0 (NE)	0.0 (NE)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	11.1 (0.00)	-16.7 (7.86)	0.0 (NE)	0.0 (NE)
	Median	11.1	-16.7	0.0	0.0
	Q1, Q3	11.1, 11.1	-22.2, -11.1	0.0, 0.0	0.0, 0.0
	Min, Max	11, 11	-22, -11	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-22.2 (0.00)	0.0 (NE)	0.0 (NE)
	Median	5.6	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, -22.2	0.0, 0.0	0.0, 0.0
	Min, Max	0, 11	-22, -22	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	11.1 (15.71)	-16.7 (7.86)	0.0 (NE)	0.0 (NE)
	Median	11.1	-16.7	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, -11.1	0.0, 0.0	0.0, 0.0
	Min, Max	0, 22	-22, -11	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			11.1 (NE)	11.1 (NE)
	Median			11.1	11.1
	Q1, Q3			11.1, 11.1	11.1, 11.1
	Min, Max			11, 11	11, 11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			11.1 (NE)	11.1 (NE)
	Median			11.1	11.1
	Q1, Q3			11.1, 11.1	11.1, 11.1
	Min, Max			11, 11	11, 11
End of Treatment	n	9	9	14	14
	Mean (SD)	6.2 (11.26)	-3.7 (21.52)	23.8 (24.21)	0.8 (21.11)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 44.4	-11.1, 11.1
	Min, Max	0, 33	-44, 33	0, 67	-33, 44

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	20.4 (29.52)	8.3 (17.81)	35.9 (24.70)	13.1 (16.31)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	0.0, 27.8	11.1, 44.4	0.0, 22.2
	Min, Max	0, 89	-22, 33	0, 89	0, 44

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		17.6 (33.58)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	17.8 (24.77)	0.0 (41.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	-100, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	21.2 (37.34)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	25.0 (40.51)	2.8 (43.71)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 50.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	12.1 (22.47)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	-100, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (33.33)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 100	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.3 (37.80)	0.0 (57.74)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (57.74)	33.3 (57.74)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 100.0	0.0, 100.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	44.4 (50.92)	44.4 (50.92)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 0	0, 0	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	14.8 (33.79)	14.8 (33.79)	42.9 (37.96)	23.8 (30.46)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	33.3 (34.82)	33.3 (34.82)	56.9 (36.83)	39.2 (35.81)
	Median	33.3	33.3	66.7	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 100.0	0.0, 66.7
	Min, Max	0, 100	0, 100	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		9.8 (15.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (30.63)	17.8 (17.21)	6.7 (18.69)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	0.0 (0.00)	-13.3 (23.31)	24.2 (33.63)	18.2 (34.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-67, 0	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-11.1 (28.87)	19.4 (30.01)	13.9 (30.01)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 100	0, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (17.25)	-4.2 (27.82)	15.2 (22.92)	9.1 (21.56)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	9.5 (16.27)	0.0 (0.00)	11.1 (16.67)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-14.3 (32.53)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (27.22)	11.1 (17.21)	5.6 (13.61)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 16.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	6.7 (14.91)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (0.00)	-11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 0	-67, 0	0, 0	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (14.70)	0.0 (23.57)	28.6 (28.81)	19.0 (31.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	19.4 (17.16)	5.6 (23.92)	35.3 (24.92)	25.5 (30.11)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		15.7 (29.15)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	6.7 (21.08)	31.1 (29.46)	13.3 (24.56)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	20.0 (17.21)	3.3 (24.60)	27.3 (29.13)	12.1 (16.82)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	25.9 (22.22)	7.4 (14.70)	30.6 (30.01)	16.7 (22.47)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	16.7 (25.20)	0.0 (17.82)	24.2 (26.21)	18.2 (22.92)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	19.0 (26.23)	9.5 (25.20)	25.9 (22.22)	18.5 (17.57)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (17.82)	0.0 (19.25)	9.5 (16.27)	4.8 (12.60)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (47.14)	16.7 (27.89)	11.1 (17.21)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-67, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	0.0 (33.33)	20.0 (18.26)	13.3 (18.26)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	50.0 (23.57)	33.3 (0.00)
	Median	0.0	0.0	50.0	33.3
	Q1, Q3	0.0, 33.3	-66.7, 0.0	33.3, 66.7	33.3, 33.3
	Min, Max	0, 33	-67, 0	33, 67	33, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	33.3 (33.33)	22.2 (38.49)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-67, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	44.4 (50.92)	33.3 (57.74)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	0.0 (0.00)	33.3 (33.33)	22.2 (38.49)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 67	0, 0	0, 67	0, 67
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (47.14)	22.2 (19.25)	11.1 (19.25)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	33.3 (47.14)	33.3 (47.14)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-33, 0	0, 67	0, 67
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	66.7 (NE)	66.7 (NE)
	Median	0.0	-16.7	66.7	66.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	66.7, 66.7	66.7, 66.7
	Min, Max	0, 0	-33, 0	67, 67	67, 67
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-33.3 (0.00)	33.3 (NE)	33.3 (NE)
	Median	16.7	-33.3	33.3	33.3
	Q1, Q3	0.0, 33.3	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	0, 33	-33, -33	33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	33.3 (47.14)	-16.7 (23.57)	33.3 (NE)	33.3 (NE)
	Median	33.3	-16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	-33.3, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 67	-33, 0	33, 33	33, 33
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-33.3 (0.00)	66.7 (NE)	66.7 (NE)
	Median	16.7	-33.3	66.7	66.7
	Q1, Q3	0.0, 33.3	-33.3, -33.3	66.7, 66.7	66.7, 66.7
	Min, Max	0, 33	-33, -33	67, 67	67, 67
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	14.8 (17.57)	3.7 (30.93)	33.3 (36.98)	16.7 (31.35)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	47.2 (22.29)	25.0 (20.72)	49.0 (33.58)	33.3 (31.18)
	Median	33.3	33.3	33.3	33.3
	Q1, Q3	33.3, 66.7	33.3, 33.3	33.3, 66.7	0.0, 66.7
	Min, Max	33, 100	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	11.1 (29.59)		9.8 (19.60)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 0.0	
	Min, Max	0, 100		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	24.4 (29.46)	13.3 (24.56)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	27.3 (35.96)	15.2 (37.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (26.06)	30.6 (36.12)	19.4 (26.43)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 100	0, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (24.80)	0.0 (17.82)	27.3 (29.13)	21.2 (30.81)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	37.0 (35.14)	33.3 (33.33)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (25.20)	23.8 (37.09)	19.0 (37.80)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (27.22)	16.7 (40.82)	11.1 (27.22)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (19.25)	-11.1 (50.92)	20.0 (29.81)	13.3 (18.26)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	0.0 (NE)	0.0 (NE)
	Median	0.0	-50.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	50.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	50.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	28.6 (36.65)	21.4 (30.96)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	16.7 (30.15)	5.6 (19.25)	51.0 (37.49)	41.2 (32.34)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 16.7	33.3, 100.0	33.3, 66.7
	Min, Max	0, 100	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	2.8 (9.62)		13.7 (23.74)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	13.3 (21.08)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	15.2 (22.92)	0.0 (25.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	7.4 (14.70)	19.4 (26.43)	5.6 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	4.2 (11.79)	15.2 (22.92)	6.1 (25.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	11.1 (23.57)	0.0 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	16.7 (40.82)	11.1 (27.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	26.2 (29.75)	11.9 (28.06)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	13.9 (17.16)	11.1 (21.71)	39.2 (33.82)	25.5 (27.71)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	8.3 (15.08)		15.7 (23.91)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 16.7		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (14.05)	20.0 (27.60)	4.4 (27.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	-3.3 (10.54)	18.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-7.4 (14.70)	19.4 (30.01)	2.8 (22.29)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 100	-33, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-8.3 (15.43)	21.2 (26.97)	6.1 (32.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	-4.8 (12.60)	11.1 (16.67)	-7.4 (22.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (16.27)	9.5 (16.27)	-9.5 (25.20)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (0.00)	11.1 (27.22)	-11.1 (34.43)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	6.7 (14.91)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	16.7 (23.57)	-16.7 (23.57)
	Median	0.0	-33.3	16.7	-16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)	-16.7 (23.57)
	Median	16.7	0.0	0.0	-16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 0	-33, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	0.0 (NE)	-33.3 (NE)
	Median	16.7	0.0	0.0	-33.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	0, 0	0, 0	-33, -33
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (0.00)	0.0 (NE)	-33.3 (NE)
	Median	0.0	-33.3	0.0	-33.3
	Q1, Q3	0.0, 0.0	-33.3, -33.3	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 0	-33, -33	0, 0	-33, -33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	0.0 (NE)	-33.3 (NE)
	Median	16.7	-16.7	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	0.0 (NE)	-33.3 (NE)
	Median	16.7	-16.7	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-33.3 (NE)
	Median			0.0	-33.3
	Q1, Q3			0.0, 0.0	-33.3, -33.3
	Min, Max			0, 0	-33, -33
Cycle 42	n	0	0	1	1
	Mean (SD)			66.7 (NE)	33.3 (NE)
	Median			66.7	33.3
	Q1, Q3			66.7, 66.7	33.3, 33.3
	Min, Max			67, 67	33, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	0.0 (0.00)	-7.4 (14.70)	14.3 (21.54)	0.0 (26.15)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 67	-67, 33

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	5.6 (12.97)	-2.8 (9.62)	39.2 (35.81)	23.5 (28.30)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 100	-33, 67

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-ia.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	53.70 (36.03)	-8.93 (6.75)	17	58.17 (33.22)	-12.75 (5.13)	3.82 (-11.92, 19.56)	0.21 (-0.64, 1.06)	0.6191

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-ia.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Eating									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	27.08 (30.18)	-11.10 (6.84)	17	29.41 (24.32)	3.42 (5.04)	-14.52 (-30.47, 1.44)	-0.75 (-1.59, 0.09)	0.0723

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-ia.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Reflux									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	4.17 (10.36)	-3.87 (2.35)	17	12.75 (20.01)	4.72 (1.91)	-8.58 (-14.10, -3.06)	-1.52 (-2.56, -0.48)	0.0036

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-ia.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Pain (OES18)									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	12.04 (18.02)	-8.04 (3.89)	17	22.88 (20.21)	-0.52 (3.02)	-7.52 (-16.84, 1.80)	-0.73 (-1.63, 0.18)	0.1083

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-ia.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble swallowing saliva									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	-1.67 (6.34)	17	17.65 (33.58)	5.04 (5.07)	-6.71 (-21.97, 8.55)	-0.39 (-1.27, 0.49)	0.3700

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

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[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-ia.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Choked when swallowing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-8.65 (5.46)	17	9.80 (15.66)	9.96 (4.07)	-18.61 (-31.24, -5.97)	-1.30 (-2.25, -0.35)	0.0060

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

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[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-ia.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dry mouth									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	7.19 (5.42)	17	15.69 (29.15)	13.10 (4.12)	-5.91 (-18.43, 6.62)	-0.42 (-1.31, 0.46)	0.3397

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with taste									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	11.11 (29.59)	-12.08 (7.60)	17	9.80 (19.60)	9.77 (5.46)	-21.84 (-38.98, -4.70)	-1.08 (-1.97, -0.19)	0.0149

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with coughing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	2.78 (9.62)	-0.18 (5.25)	17	13.73 (23.74)	4.28 (3.89)	-4.46 (-17.06, 8.14)	-0.32 (-1.20, 0.57)	0.4723

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

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[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble talking									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	8.33 (15.08)	-3.39 (5.29)	17	15.69 (23.91)	7.76 (3.93)	-11.15 (-23.89, 1.59)	-0.76 (-1.64, 0.12)	0.0818

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

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[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	13	7 (53.8)	2.9 (0.1, NE)	17	5 (29.4)	NR (6.4, NE)	3.765 (0.748, 18.944)	0.0754
Eating	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	NR (0.8, NE)	0.269 (0.030, 2.390)	0.2122
Reflux	13	2 (15.4)	NR (1.9, NE)	17	6 (35.3)	NR (1.4, NE)	0.499 (0.090, 2.772)	0.4197
Pain	13	1 (7.7)	NR (NE, NE)	17	5 (29.4)	24.4 (0.8, NE)	0.648 (0.055, 7.567)	0.7273
Trouble Swallowing Saliva	13	1 (7.7)	NR (NE, NE)	17	6 (35.3)	NR (1.0, NE)	0.242 (0.026, 2.297)	0.1857
Choked When Swallowing	13	1 (7.7)	NR (2.3, NE)	17	5 (29.4)	NR (1.5, NE)	0.324 (0.035, 3.050)	0.3032

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dry Mouth	13	3 (23.1)	NR (2.3, NE)	17	9 (52.9)	2.2 (0.7, NE)	0.393 (0.095, 1.630)	0.1859
Trouble With Taste	13	2 (15.4)	NR (2.8, NE)	17	8 (47.1)	3.3 (0.8, NE)	0.279 (0.056, 1.384)	0.0975
Trouble With Coughing	13	3 (23.1)	26.0 (0.7, NE)	17	4 (23.5)	NR (2.2, NE)	0.648 (0.103, 4.061)	0.6402
Trouble Talking	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (3.2, NE)	0.000 (0.000, NE)	0.2489

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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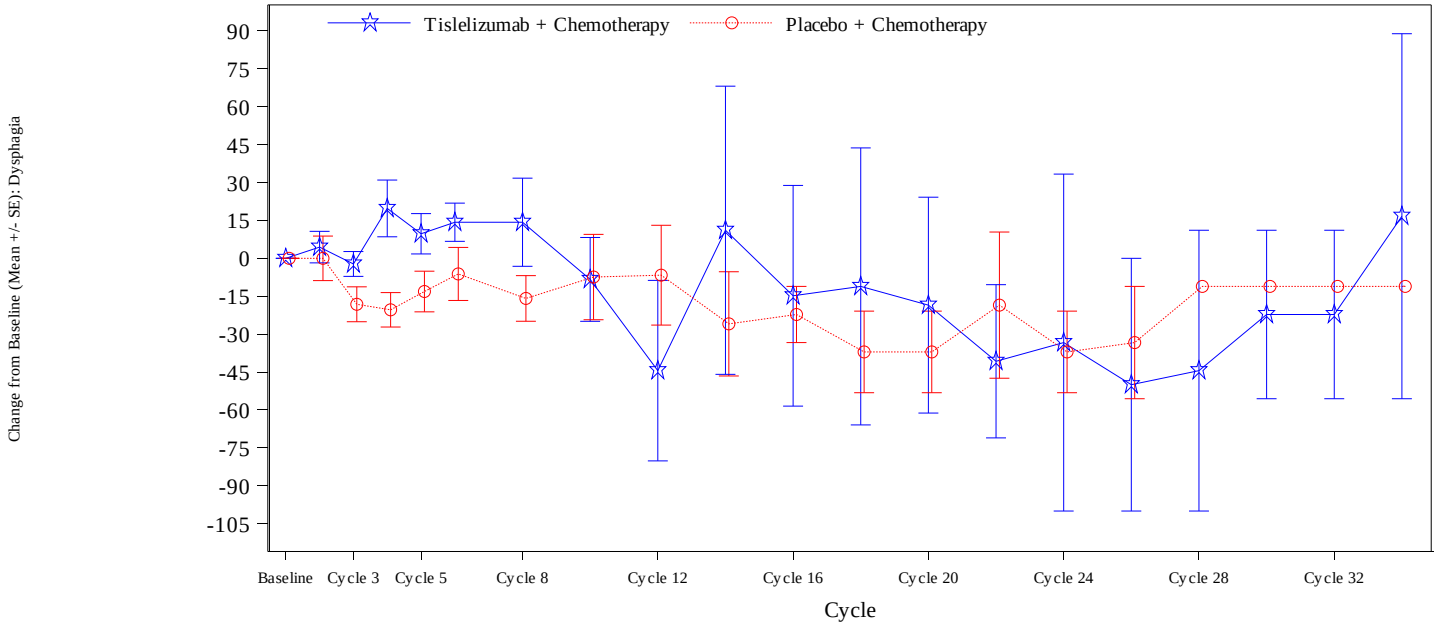
Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-2-series-o18-pop1-ia.rtf

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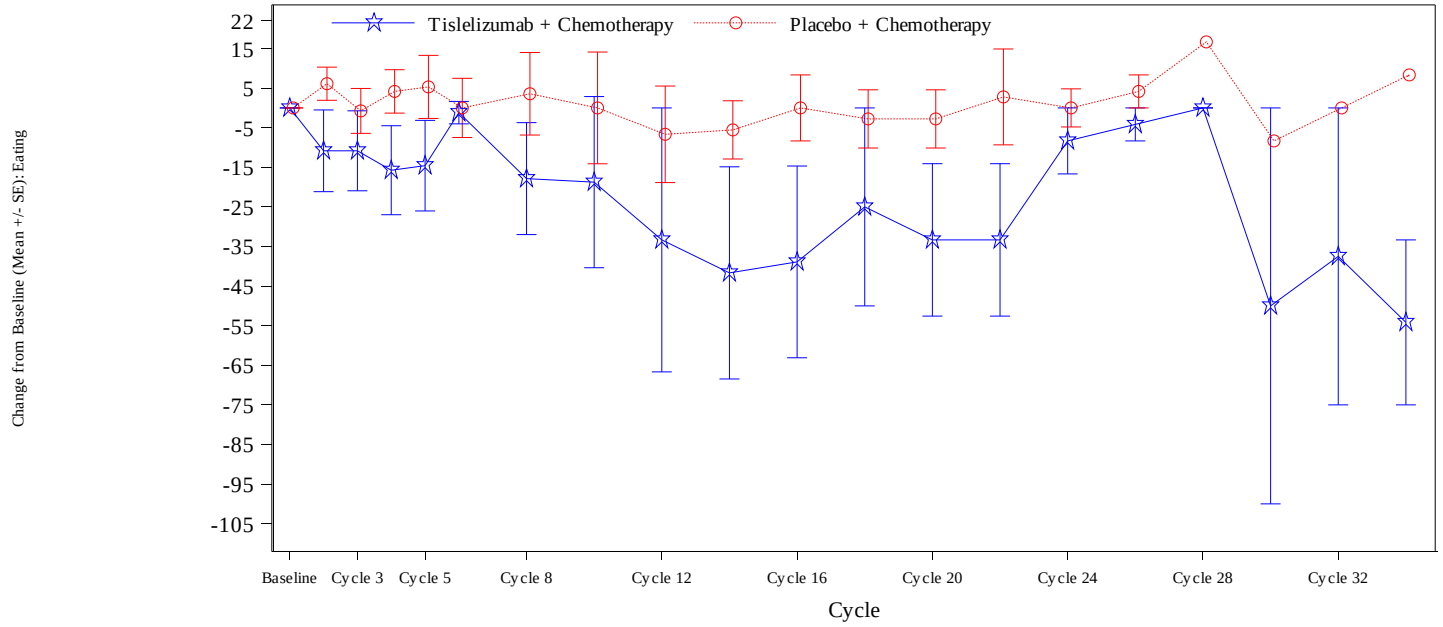
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
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Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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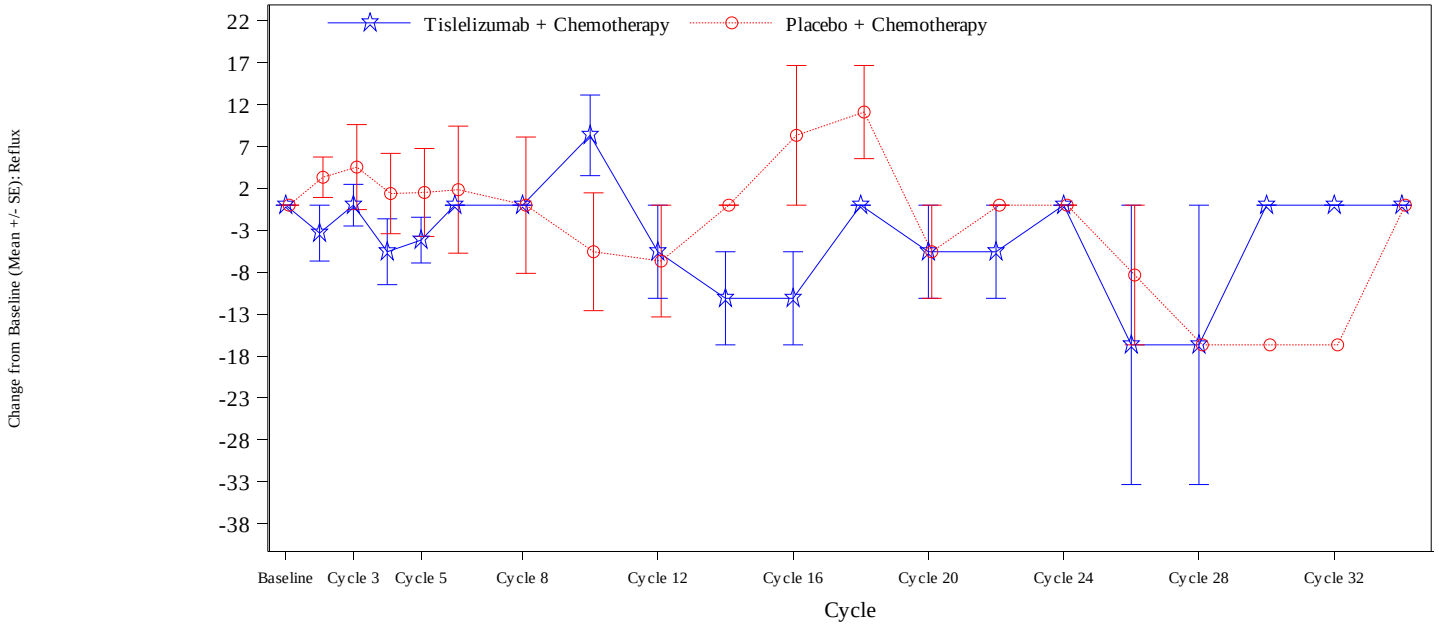

No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
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Figure 14.2.7.2:
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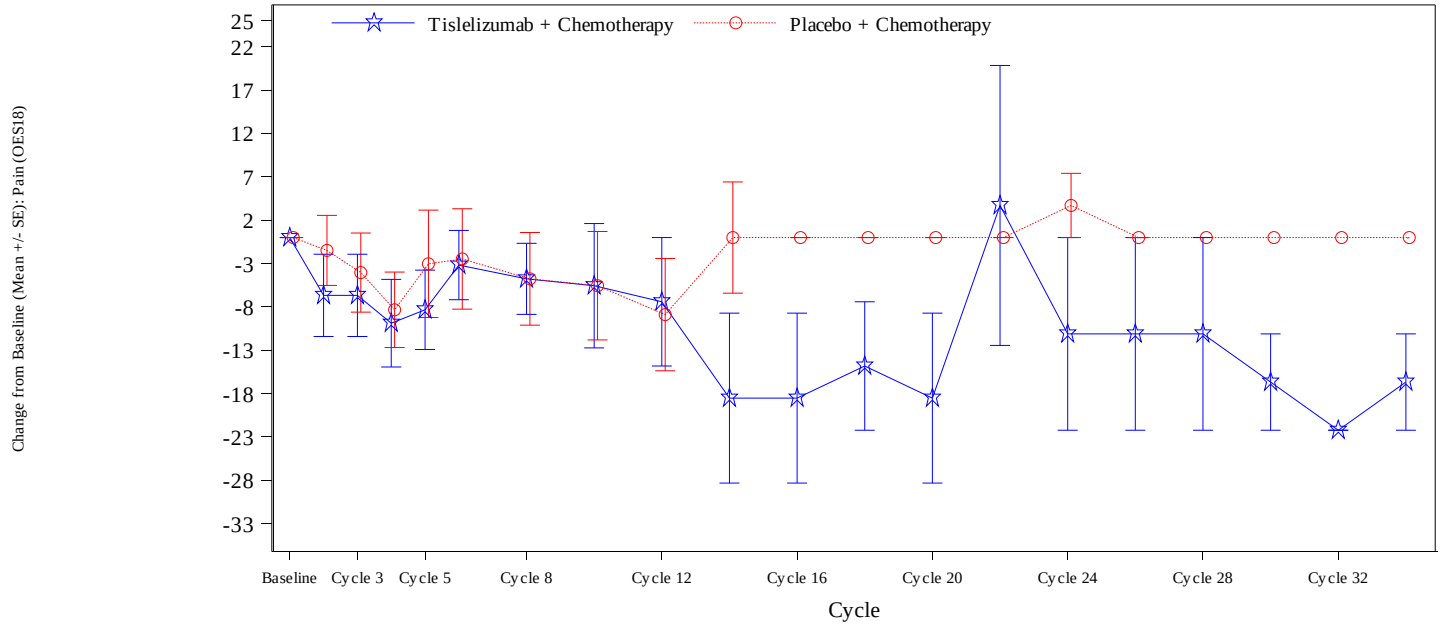

No. of Patients

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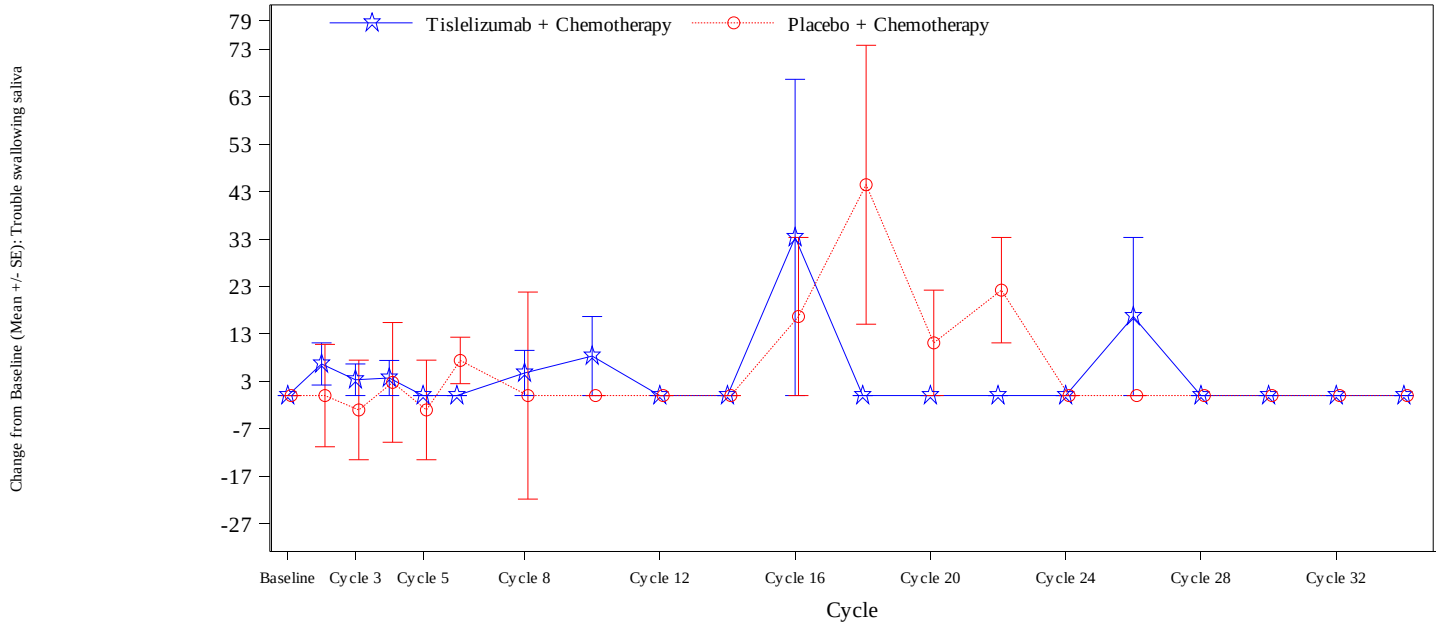

No. of Patients

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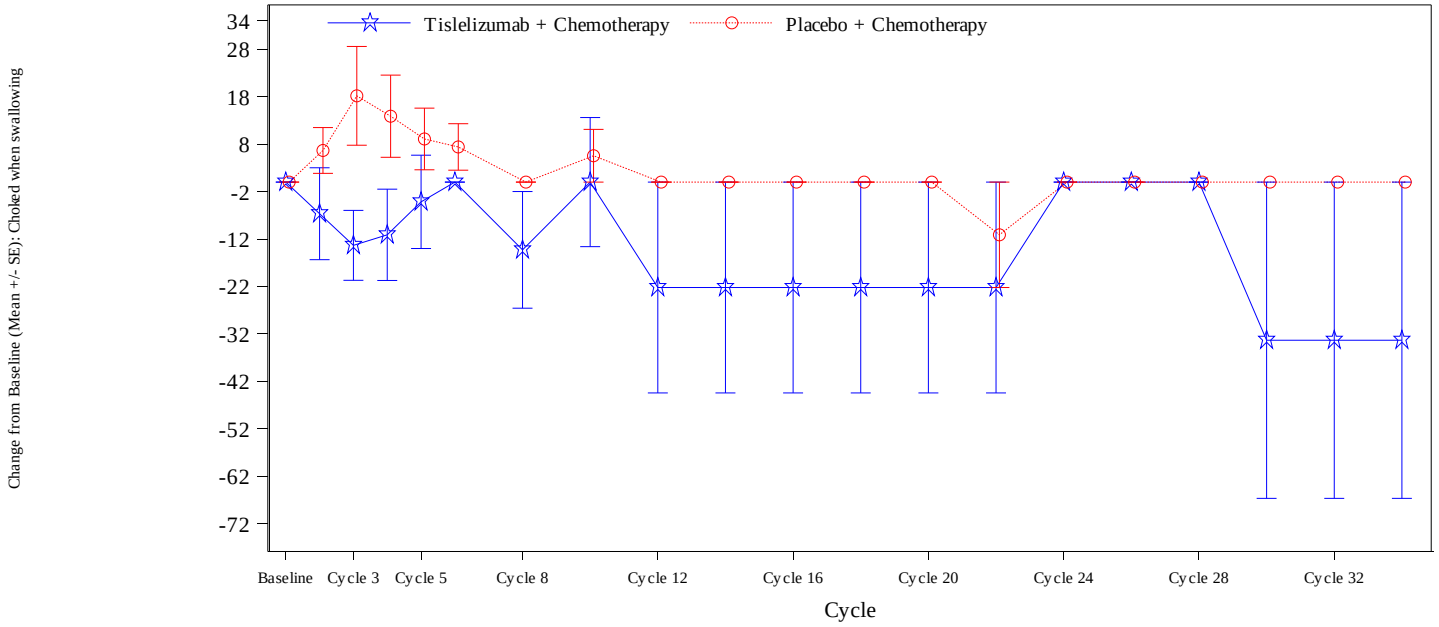

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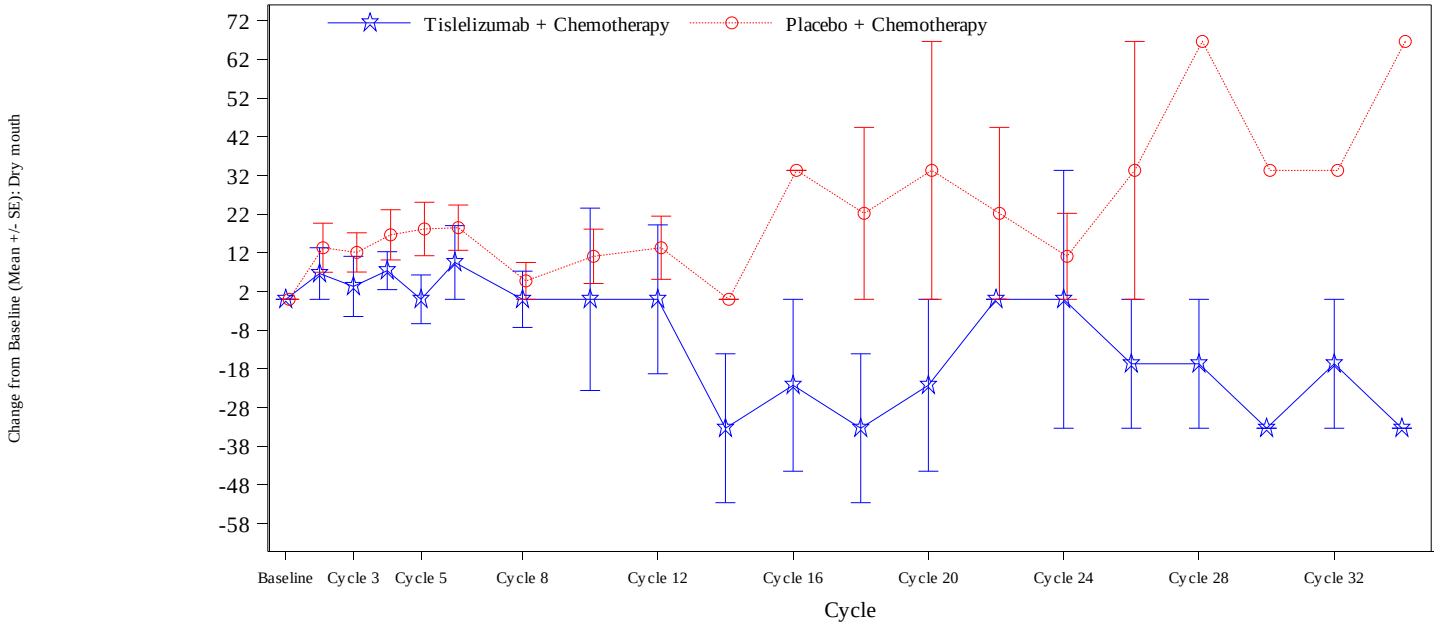

No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
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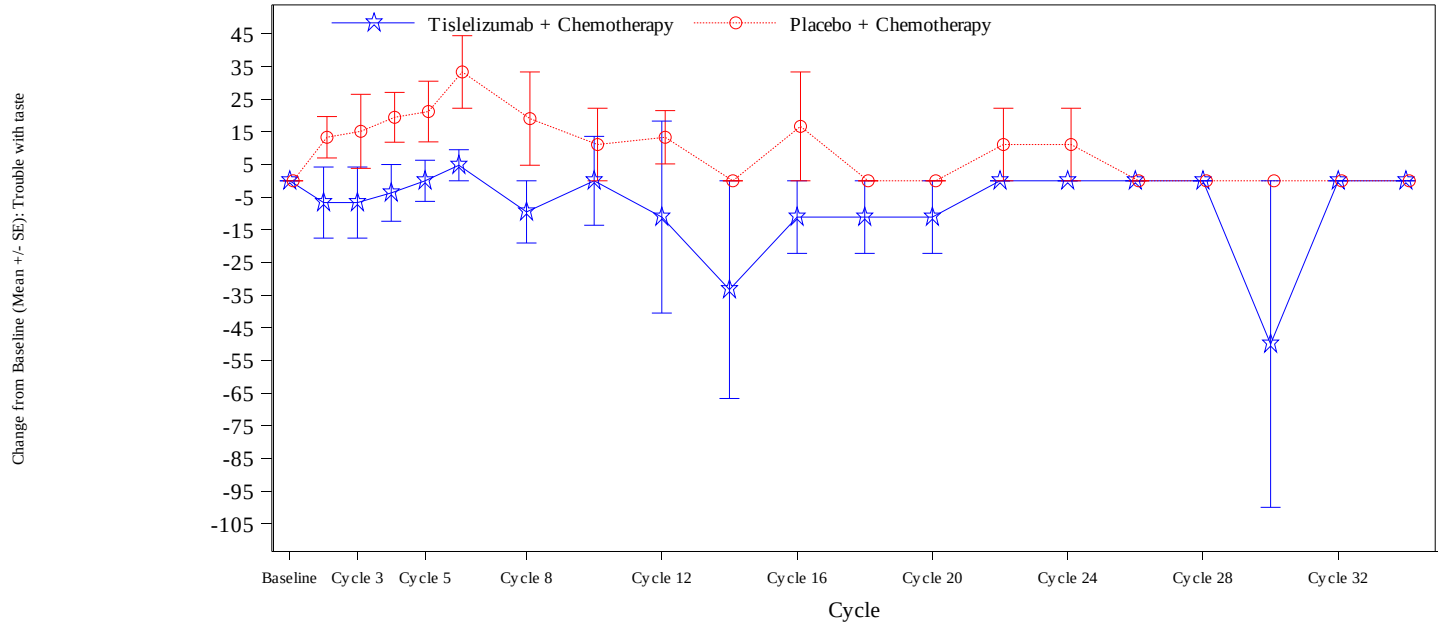

No. of Patients

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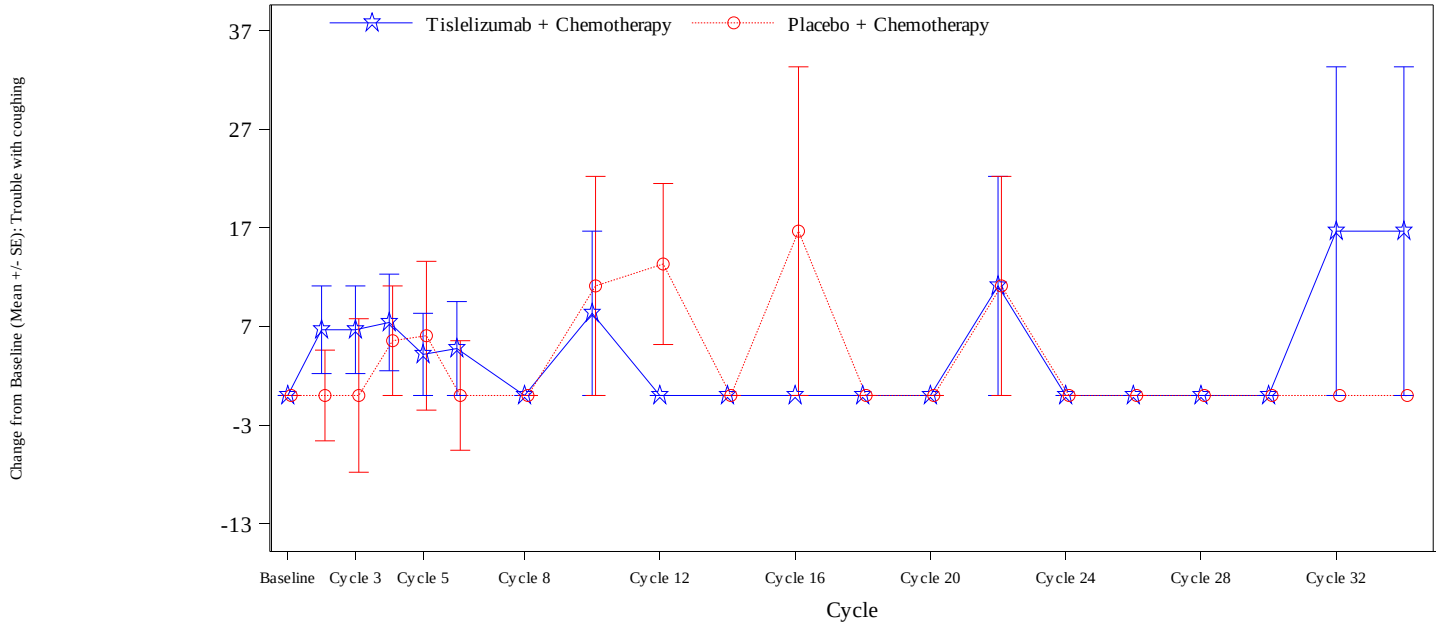
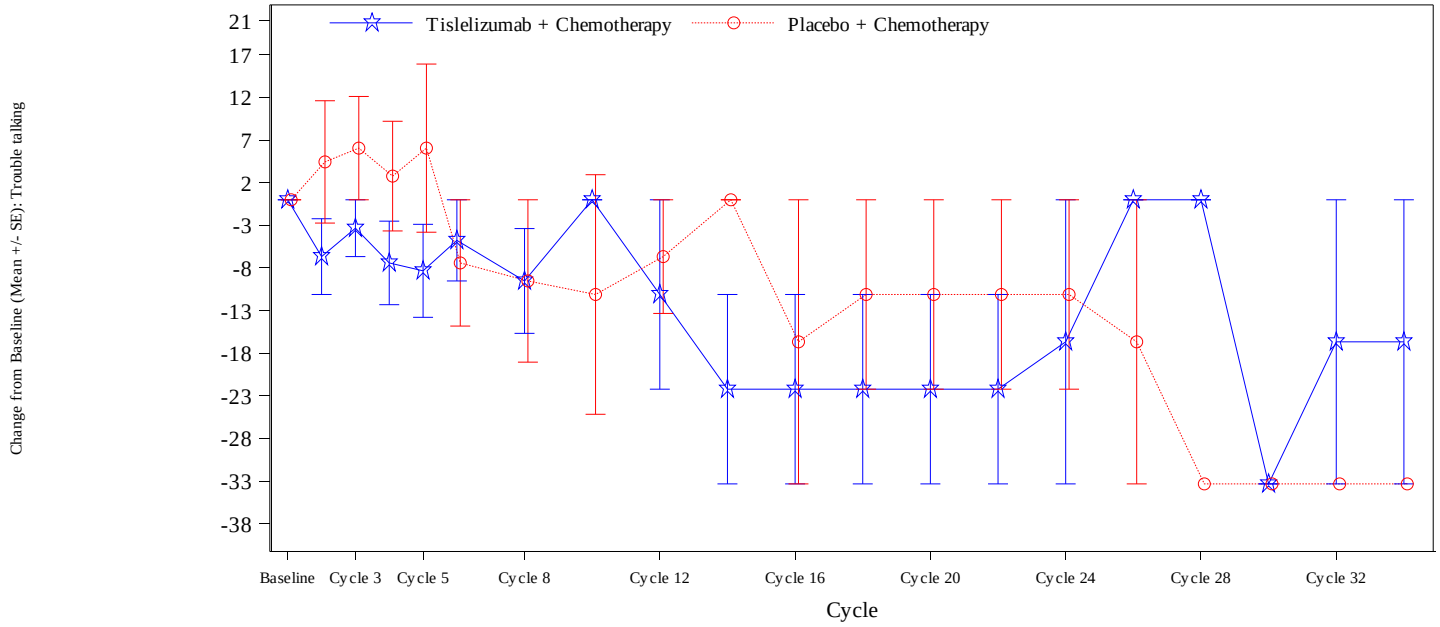


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-2-series-o18-pop1-ia.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

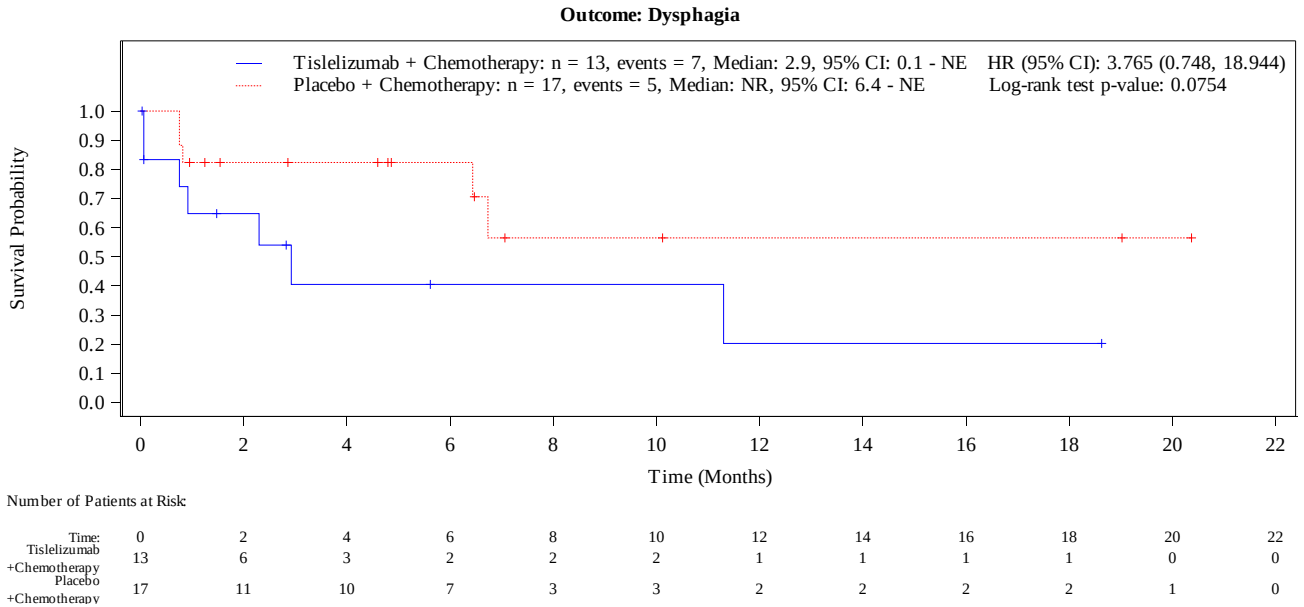


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

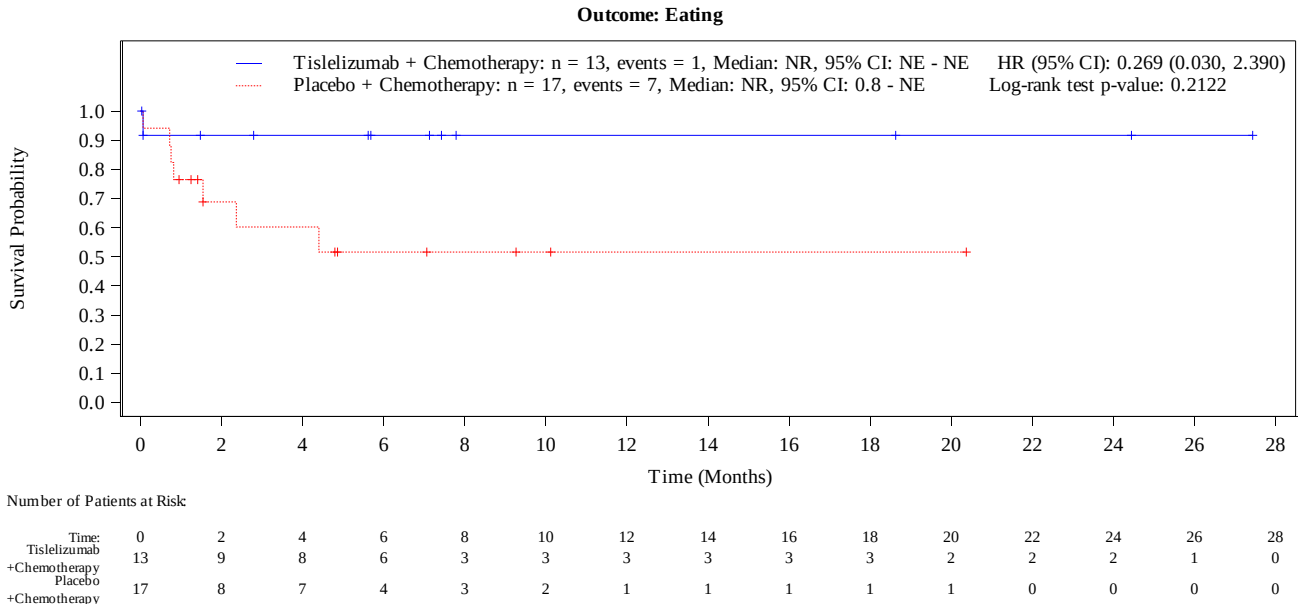
Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-2-series-o18-pop1-ia.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



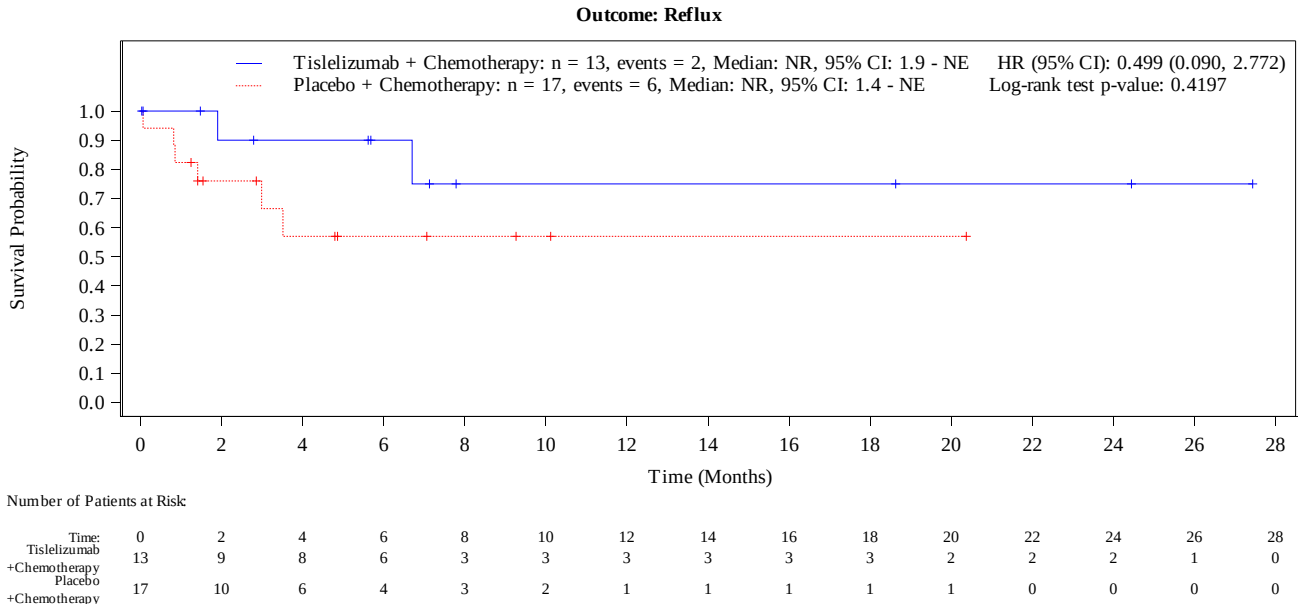
Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-ia.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-ia.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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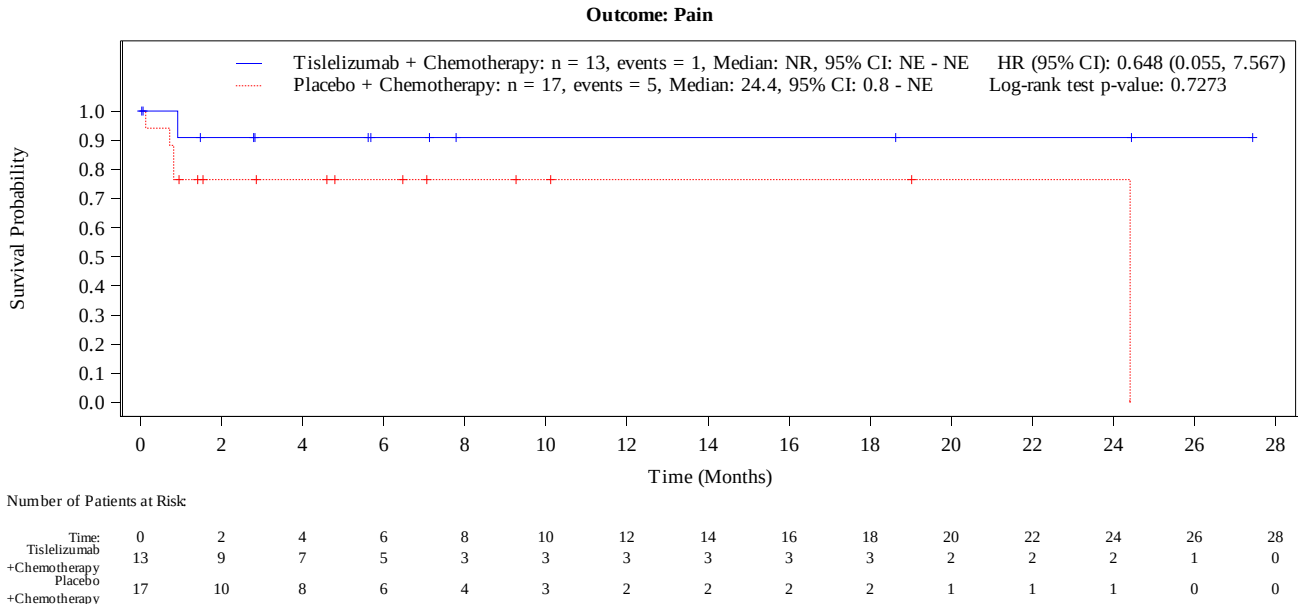
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-ia.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
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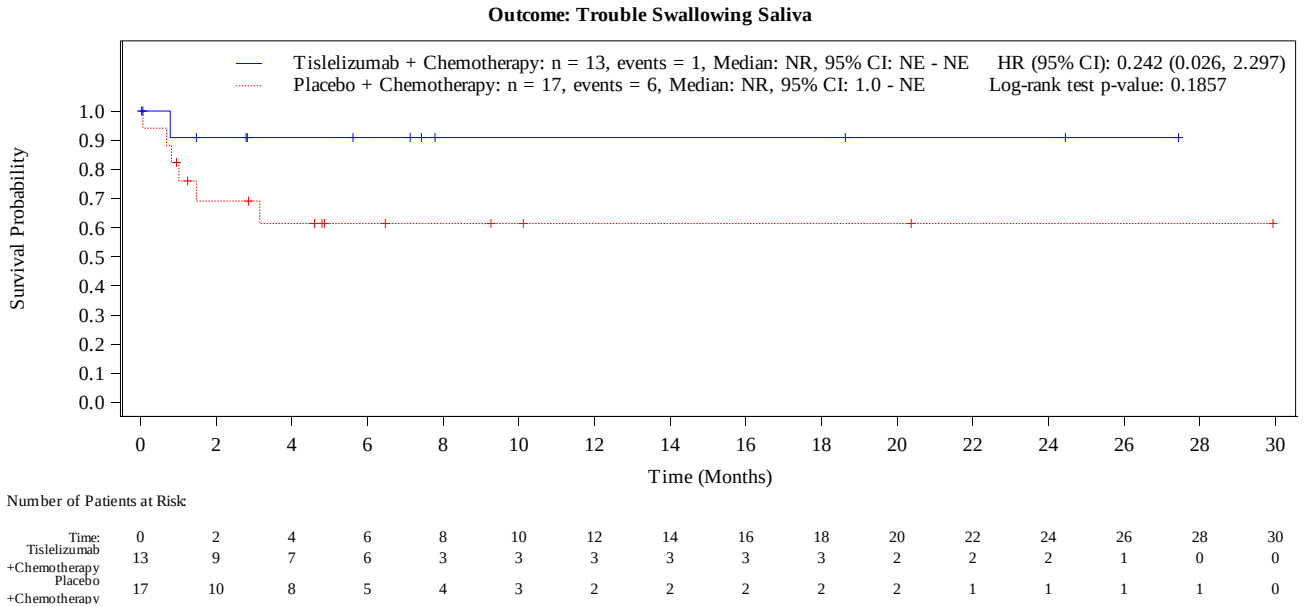
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-ia.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
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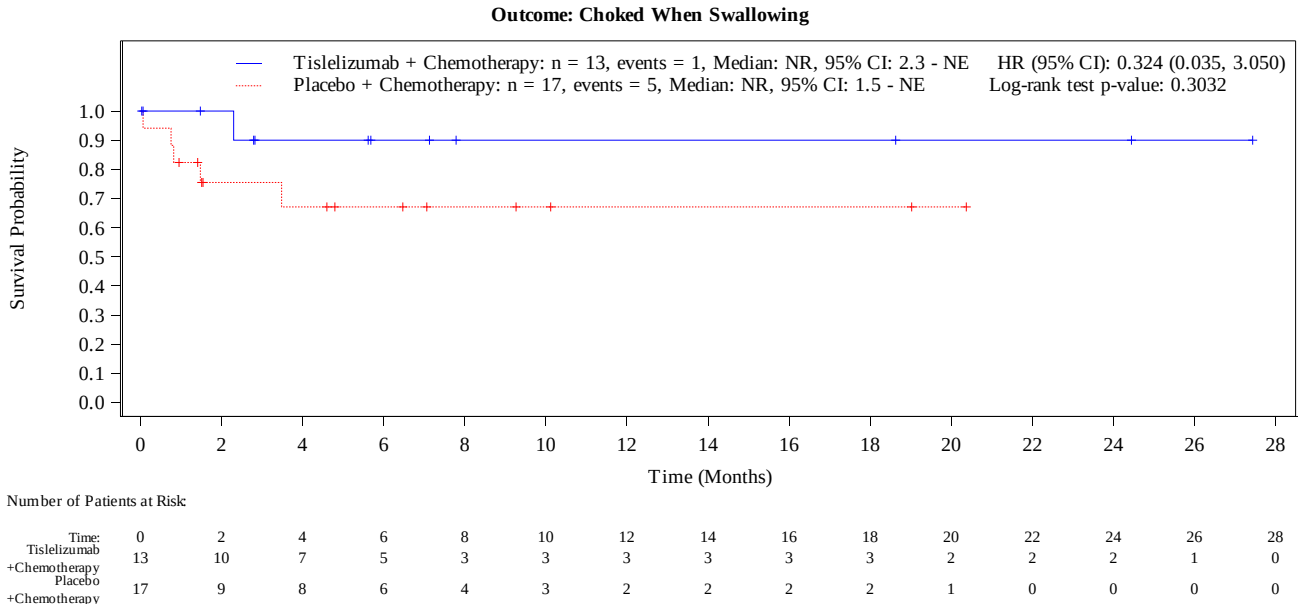
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
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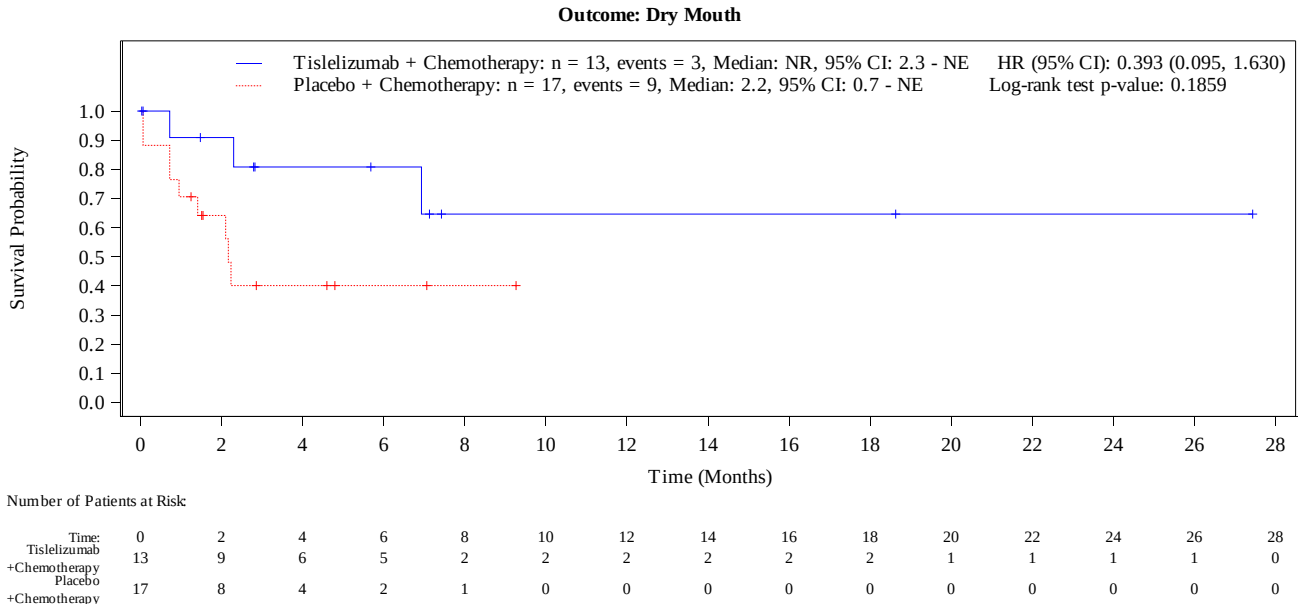
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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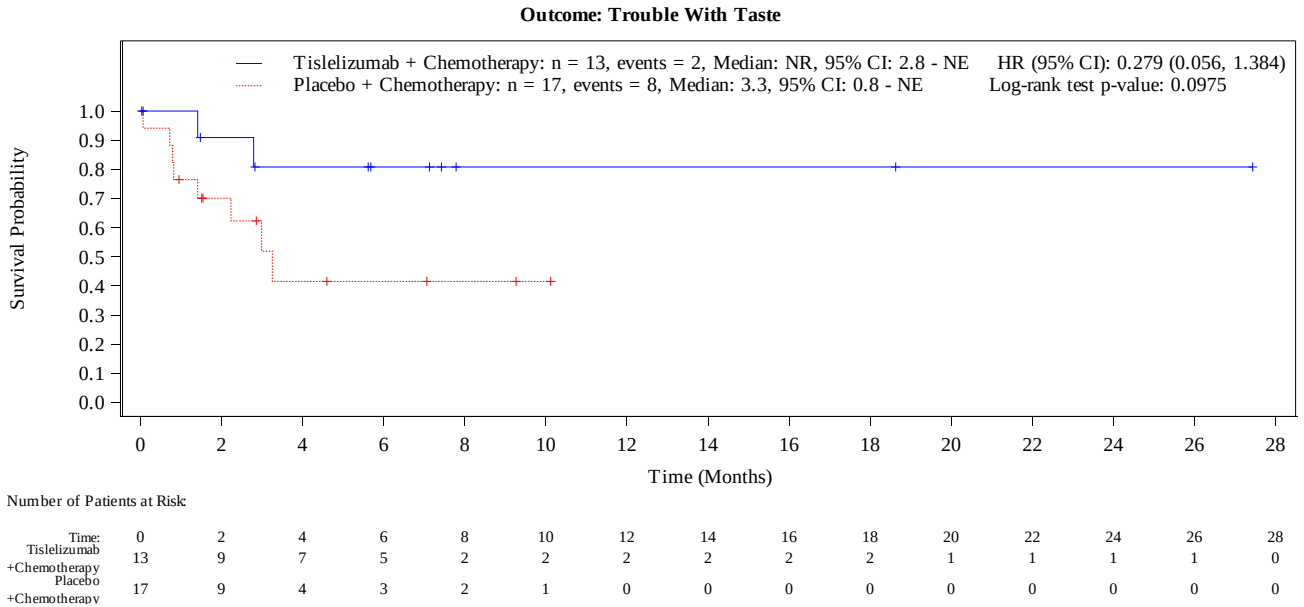
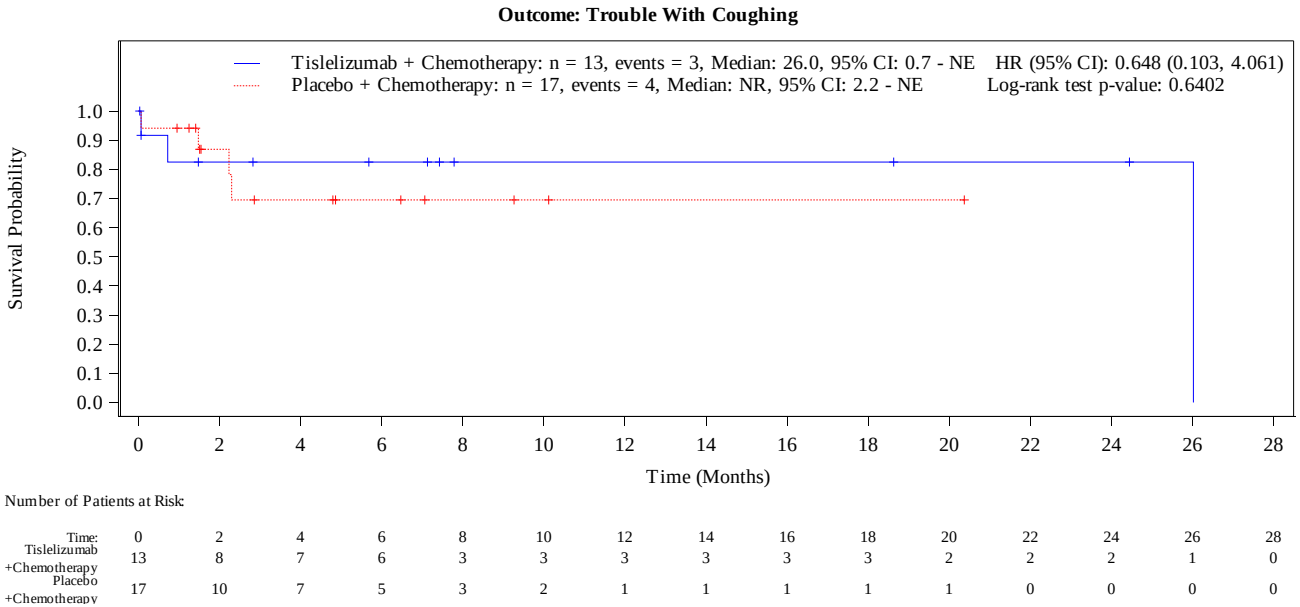
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-ia.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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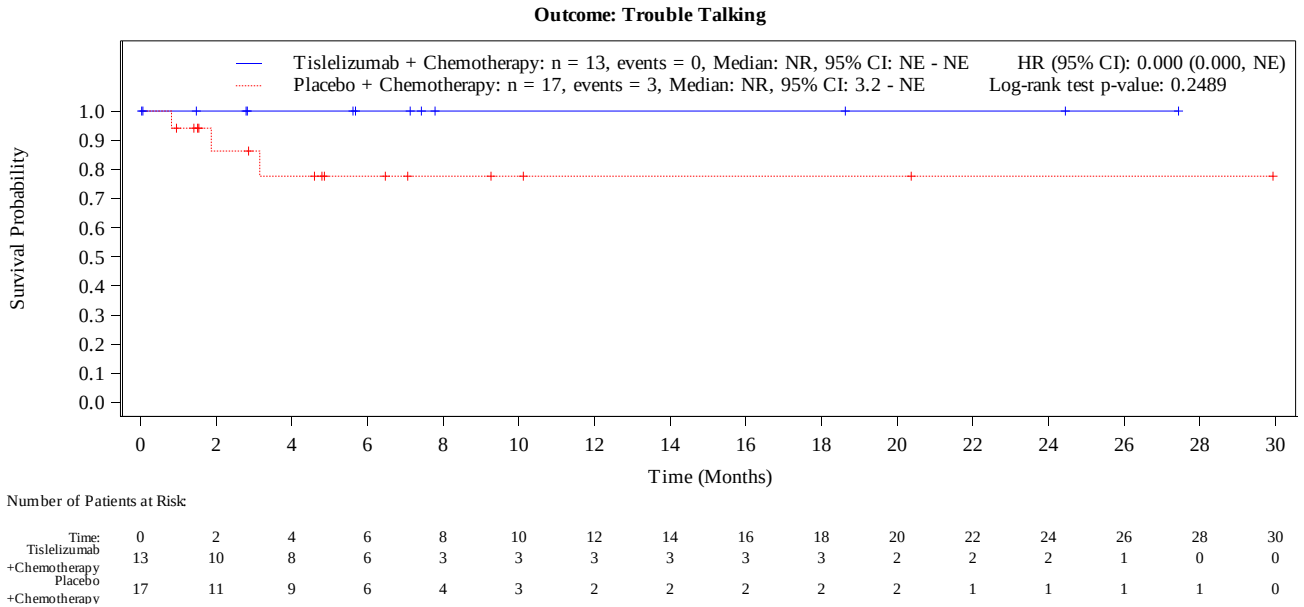
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-ia.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-ia.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	5 (55.6)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	4 (36.4)	--	--	--
Female	4	3 (75.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-ia.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	2 (20.0)	--	--	--
1	6	3 (50.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	3 (42.9)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-ia.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-ia.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	1 (11.1)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	4 (57.1)	--	--	--
No	9	1 (11.1)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-ia.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	1 (11.1)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-ia.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

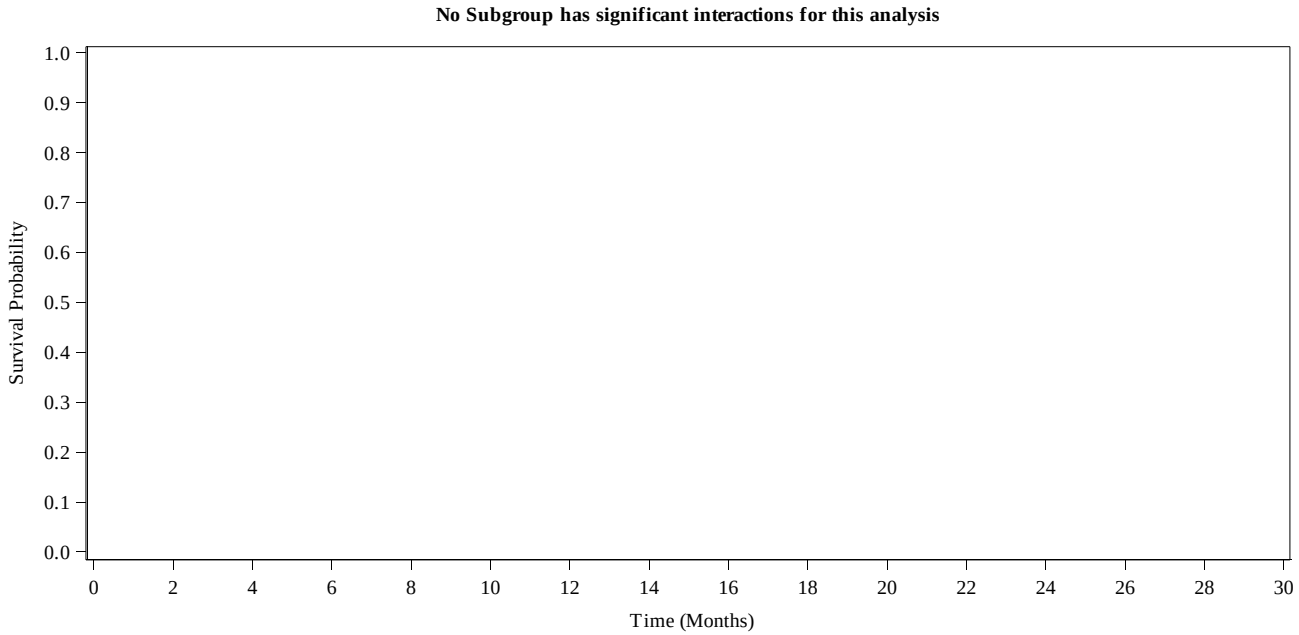
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-ia.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-2-2-s-km-tteqs-subgrp-oes-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	70.6 (26.11)		64.8 (19.76)	
	Median	77.0		69.0	
	Q1, Q3	51.0, 90.0		51.0, 80.0	
	Min, Max	13, 98		20, 92	
Cycle 2	n	10	10	15	15
	Mean (SD)	77.7 (17.80)	7.4 (29.15)	67.8 (19.24)	3.7 (15.57)
	Median	80.0	2.0	75.0	5.0
	Q1, Q3	76.0, 89.0	-10.0, 13.0	61.0, 80.0	-9.0, 15.0
	Min, Max	40, 98	-39, 63	20, 88	-23, 28
Cycle 3	n	10	10	12	12
	Mean (SD)	79.2 (12.62)	8.9 (20.30)	69.1 (23.00)	2.5 (20.25)
	Median	81.0	6.0	75.5	2.0
	Q1, Q3	69.0, 90.0	-8.0, 15.0	65.0, 84.0	-9.5, 19.5
	Min, Max	59, 95	-10, 47	20, 95	-33, 27

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	78.4 (18.41)	9.1 (16.47)	65.8 (22.06)	-0.8 (20.74)
	Median	80.0	8.0	75.0	-0.5
	Q1, Q3	79.0, 92.0	-3.0, 17.0	55.0, 80.0	-17.5, 16.0
	Min, Max	39, 96	-11, 39	21, 91	-31, 35
Cycle 5	n	8	8	11	11
	Mean (SD)	80.9 (14.97)	9.4 (17.34)	72.0 (16.73)	3.9 (20.78)
	Median	85.0	9.0	75.0	4.0
	Q1, Q3	74.5, 90.0	-6.5, 22.0	70.0, 80.0	-10.0, 23.0
	Min, Max	50, 98	-11, 37	31, 100	-30, 35
Cycle 6	n	8	8	9	9
	Mean (SD)	79.9 (16.00)	8.4 (16.29)	73.0 (19.69)	1.9 (22.62)
	Median	84.0	8.5	76.0	0.0
	Q1, Q3	72.5, 90.5	-7.5, 20.0	70.0, 80.0	-12.0, 24.0
	Min, Max	48, 97	-10, 35	27, 100	-34, 31

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	80.6 (19.26)	9.6 (15.74)	81.3 (9.23)	6.0 (16.64)
	Median	87.0	5.0	80.0	0.0
	Q1, Q3	75.0, 95.0	-3.0, 27.0	79.0, 81.0	-9.0, 20.0
	Min, Max	40, 95	-8, 34	69, 100	-12, 35
Cycle 10	n	4	4	6	6
	Mean (SD)	79.0 (27.22)	18.5 (18.16)	78.7 (15.33)	4.2 (22.66)
	Median	88.0	16.0	80.0	4.0
	Q1, Q3	60.5, 97.5	3.5, 33.5	79.0, 81.0	-10.0, 21.0
	Min, Max	40, 100	2, 40	52, 100	-29, 35
Cycle 12	n	3	3	5	5
	Mean (SD)	63.7 (25.11)	13.0 (18.52)	79.0 (13.06)	8.0 (24.58)
	Median	61.0	20.0	79.0	7.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	75.0, 86.0	-11.0, 30.0
	Min, Max	40, 90	-8, 27	60, 95	-21, 35

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	77.7 (22.23)	27.0 (30.81)	76.3 (6.35)	3.0 (16.09)
	Median	90.0	39.0	80.0	1.0
	Q1, Q3	52.0, 91.0	-8.0, 50.0	69.0, 80.0	-12.0, 20.0
	Min, Max	52, 91	-8, 50	69, 80	-12, 20
Cycle 16	n	3	3	2	2
	Mean (SD)	71.0 (19.00)	20.3 (24.95)	74.0 (7.07)	-11.5 (0.71)
	Median	71.0	30.0	74.0	-11.5
	Q1, Q3	52.0, 90.0	-8.0, 39.0	69.0, 79.0	-12.0, -11.0
	Min, Max	52, 90	-8, 39	69, 79	-12, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	63.3 (25.17)	12.7 (18.34)	76.7 (5.77)	-6.7 (6.66)
	Median	60.0	19.0	80.0	-10.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	70.0, 80.0	-11.0, 1.0
	Min, Max	40, 90	-8, 27	70, 80	-11, 1

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	75.0 (21.79)	24.3 (28.22)	80.3 (0.58)	-3.0 (6.08)
	Median	85.0	37.0	80.0	0.0
	Q1, Q3	50.0, 90.0	-8.0, 44.0	80.0, 81.0	-10.0, 1.0
	Min, Max	50, 90	-8, 44	80, 81	-10, 1
Cycle 22	n	3	3	3	3
	Mean (SD)	70.3 (30.01)	19.7 (15.37)	76.3 (7.23)	-7.0 (13.08)
	Median	71.0	27.0	80.0	-1.0
	Q1, Q3	40.0, 100.0	2.0, 30.0	68.0, 81.0	-22.0, 2.0
	Min, Max	40, 100	2, 30	68, 81	-22, 2
Cycle 24	n	2	2	3	3
	Mean (SD)	86.0 (7.07)	16.5 (33.23)	78.0 (7.21)	-5.3 (13.05)
	Median	86.0	16.5	80.0	-1.0
	Q1, Q3	81.0, 91.0	-7.0, 40.0	70.0, 84.0	-20.0, 5.0
	Min, Max	81, 91	-7, 40	70, 84	-20, 5

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	3	3	2	2
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	83.0 (4.24)	-1.5 (3.54)
	Median	71.0	30.0	83.0	-1.5
	Q1, Q3	50.0, 90.0	-8.0, 37.0	80.0, 86.0	-4.0, 1.0
	Min, Max	50, 90	-8, 37	80, 86	-4, 1
Cycle 28	n	3	3	1	1
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	71.0 (NE)	-19.0 (NE)
	Median	71.0	30.0	71.0	-19.0
	Q1, Q3	50.0, 90.0	-8.0, 37.0	71.0, 71.0	-19.0, -19.0
	Min, Max	50, 90	-8, 37	71, 71	-19, -19
Cycle 30	n	2	2	1	1
	Mean (SD)	65.5 (21.92)	38.5 (2.12)	79.0 (NE)	-11.0 (NE)
	Median	65.5	38.5	79.0	-11.0
	Q1, Q3	50.0, 81.0	37.0, 40.0	79.0, 79.0	-11.0, -11.0
	Min, Max	50, 81	37, 40	79, 79	-11, -11

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	66.5 (21.92)	39.5 (2.12)	81.0 (NE)	-9.0 (NE)
	Median	66.5	39.5	81.0	-9.0
	Q1, Q3	51.0, 82.0	38.0, 41.0	81.0, 81.0	-9.0, -9.0
	Min, Max	51, 82	38, 41	81, 81	-9, -9
Cycle 34	n	2	2	1	1
	Mean (SD)	64.5 (21.92)	37.5 (2.12)	87.0 (NE)	-3.0 (NE)
	Median	64.5	37.5	87.0	-3.0
	Q1, Q3	49.0, 80.0	36.0, 39.0	87.0, 87.0	-3.0, -3.0
	Min, Max	49, 80	36, 39	87, 87	-3, -3
Cycle 36	n	1	1	1	1
	Mean (SD)	49.0 (NE)	36.0 (NE)	70.0 (NE)	-20.0 (NE)
	Median	49.0	36.0	70.0	-20.0
	Q1, Q3	49.0, 49.0	36.0, 36.0	70.0, 70.0	-20.0, -20.0
	Min, Max	49, 49	36, 36	70, 70	-20, -20

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			95.0 (NE)	5.0 (NE)
	Median			95.0	5.0
	Q1, Q3			95.0, 95.0	5.0, 5.0
	Min, Max			95, 95	5, 5
Cycle 40	n	0	0	1	1
	Mean (SD)			70.0 (NE)	-20.0 (NE)
	Median			70.0	-20.0
	Q1, Q3			70.0, 70.0	-20.0, -20.0
	Min, Max			70, 70	-20, -20
Cycle 42	n	0	0	1	1
	Mean (SD)			70.0 (NE)	-20.0 (NE)
	Median			70.0	-20.0
	Q1, Q3			70.0, 70.0	-20.0, -20.0
	Min, Max			70, 70	-20, -20

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			65.0 (NE)	-25.0 (NE)
	Median			65.0	-25.0
	Q1, Q3			65.0, 65.0	-25.0, -25.0
	Min, Max			65, 65	-25, -25
End of Treatment	n	9	9	14	14
	Mean (SD)	68.8 (25.21)	-7.4 (32.80)	62.2 (26.18)	-1.4 (18.36)
	Median	77.0	-8.0	70.0	0.5
	Q1, Q3	60.0, 82.0	-13.0, 8.0	48.0, 78.0	-9.0, 10.0
	Min, Max	10, 94	-80, 41	10, 100	-40, 25

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	59.4 (25.75)	-11.2 (26.27)	55.3 (20.11)	-9.5 (17.46)
	Median	60.5	-8.0	60.0	-3.0
	Q1, Q3	40.0, 80.0	-11.5, 1.0	49.0, 67.0	-25.0, 2.0
	Min, Max	10, 94	-80, 26	10, 85	-40, 15

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-ia.rtf

Table 14.2.6.5.1.1:
EQ-5D-VAS: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
EQ-5D VAS									
Cycle 6	8		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	70.58 (26.11)	5.88 (4.76)	17	64.76 (19.76)	3.75 (3.66)	2.13 (-8.79, 13.05)	0.17 (-0.68, 1.01)	0.6902

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+ chemotherapy arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-5-1-1-eff-mmrmqs-vas-pop1-ia.rtf

Table 14.2.6.5.1.2:
Analyses of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	13	1 (7.7)	NR (NE, NE)	17	4 (23.5)	14.7 (3.2, NE)	0.636 (0.066, 6.122)	0.6928

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

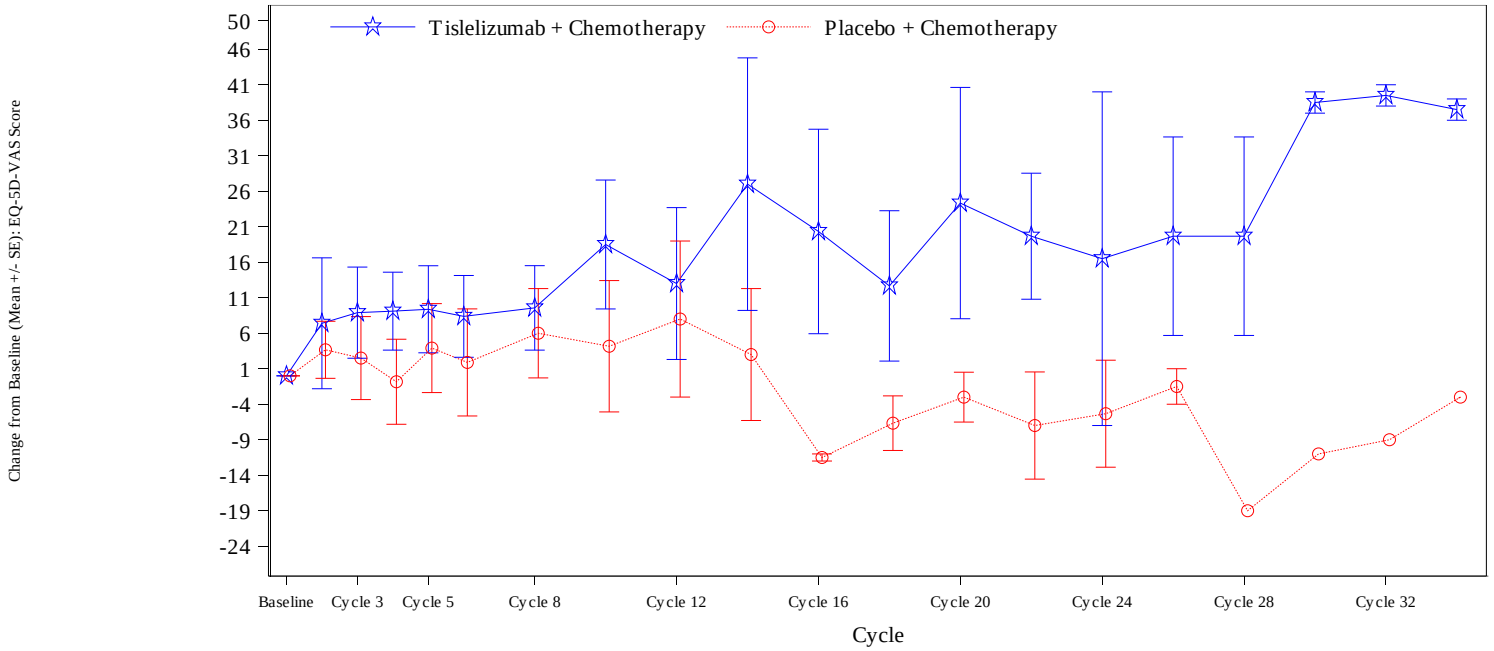
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-5-1-2-eff-tte-qlq-vas-pop1-ia.rtf

Figure 14.2.7.4:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

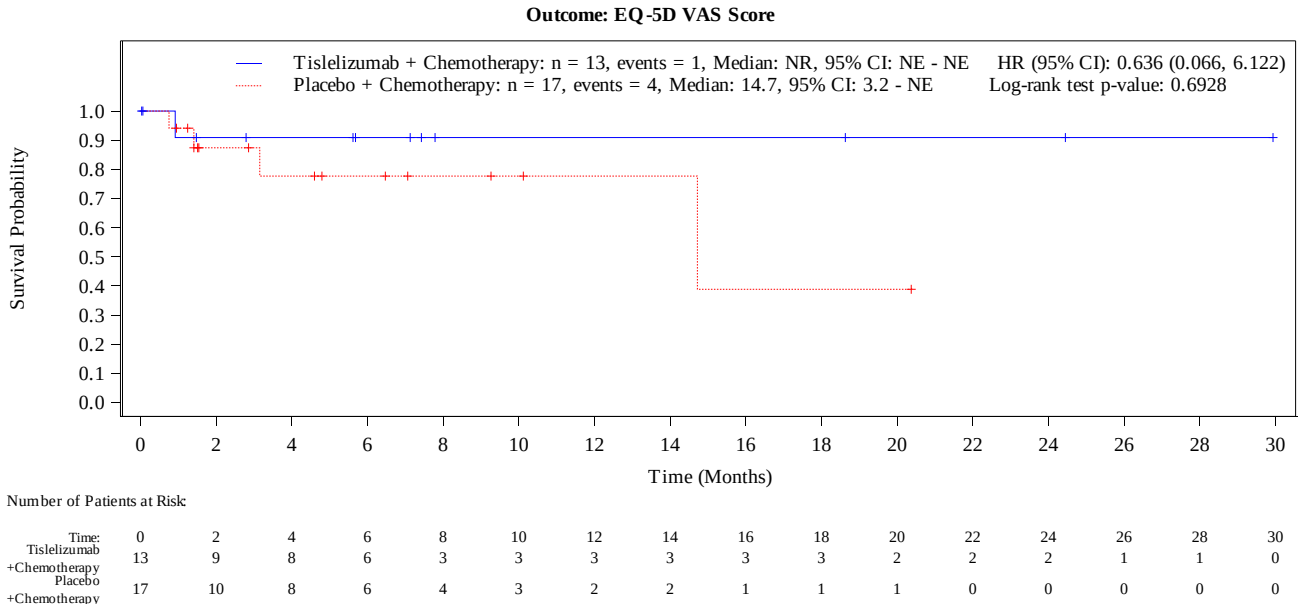


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	8	7	4	3	3	3	3	3	3	2	3	3	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-4-series-eq5d-pop1-ia.rtf

Figure 14.2.7.4.2:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-4-2-km-qs-vas-pop1-ia.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-5-1-2-s-eff-tteqs-subgrp-vas-pop1-ia.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

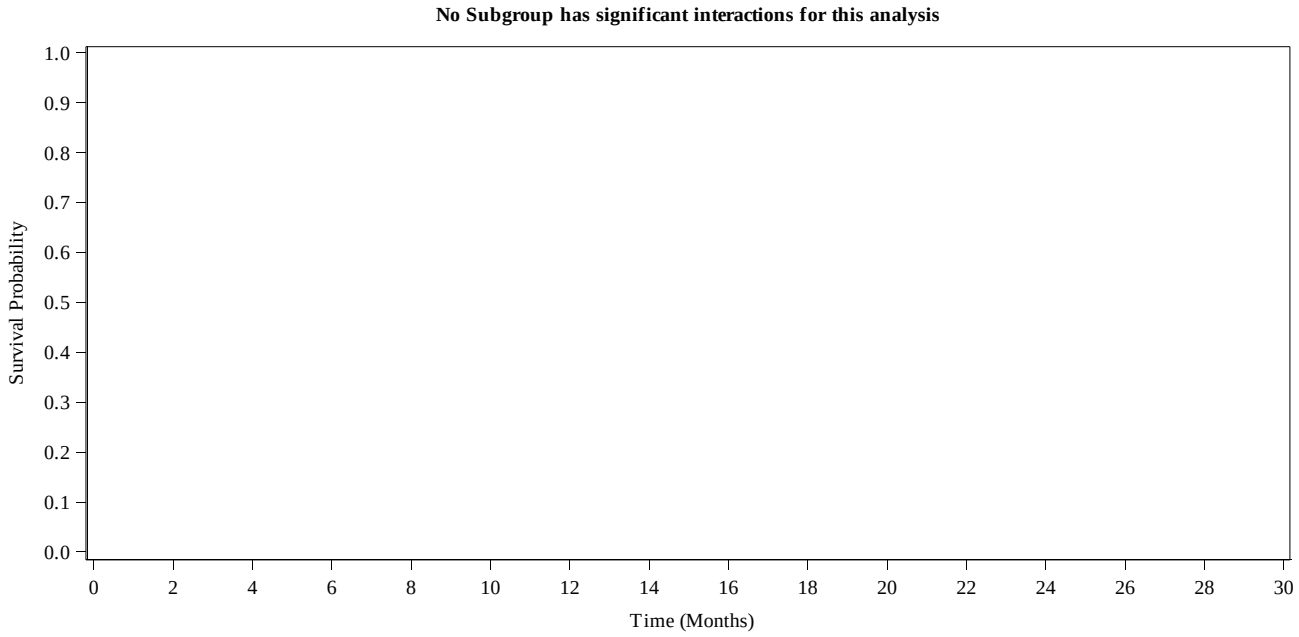
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-5-1-2-s-eff-tteqs-subgrp-vas-pop1-ia.rtf

Figure 14.2.7.4.2.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-4-2-s-km-tteqs-subgrp-vas-pop1-ia.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Patients with Any Subsequent Anti-Cancer Therapy, n (%)	8 (61.5)	13 (76.5)
Radiotherapy	1 (7.7)	5 (29.4)
Procedure or Surgery	1 (7.7)	2 (11.8)
Systemic Therapy	8 (61.5)	12 (70.6)
Immunotherapy	4 (30.8)	7 (41.2)
Time to First Post-Treatment Anti-Cancer Therapy (months)		
n	8	13
Mean (SD)	1.58 (1.407)	2.05 (2.757)
Median	0.94	1.61
Q1, Q3	0.69, 2.28	0.56, 2.07
Min, Max	0.6, 4.3	0.3, 10.8

Source: ADCM, ADPR, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.
Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-ia.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Time to First Post-Treatment Immunotherapy (months)		
n	4	7
Mean (SD)	4.94 (5.508)	2.70 (2.322)
Median	3.45	2.63
Q1, Q3	0.69, 9.18	0.56, 4.27
Min, Max	0.6, 12.3	0.3, 6.8
Post-Treatment Anti-Cancer Therapy Duration (months)		
Systemic Therapy		
n	8	12
Mean (SD)	8.30 (5.308)	4.05 (4.030)
Median	7.28	2.89
Q1, Q3	4.06, 13.57	0.92, 6.06
Min, Max	1.2, 15.3	0.0, 12.4
Patients with Ongoing Anti-Cancer Systemic Therapy at Data Cutoff, n (%)	2 (15.4)	3 (17.6)

Source: ADCM, ADPR, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Percentages were based on N.

Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.

Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-ia.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Immunotherapy		
n	4	7
Mean (SD)	2.15 (1.988)	2.92 (3.304)
Median	1.41	1.64
Q1, Q3	0.89, 3.42	0.03, 7.62
Min, Max	0.7, 5.1	0.0, 7.6
Patients with Ongoing Immunotherapy at Data Cutoff, n (%)	0 (0.0)	1 (5.9)

Source: ADCM, ADPR, ADBASE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.
Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-ia.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Duration of Treatment (month) [a]			
n	13	17	30
Mean (SD)	10.69 (10.765)	7.41 (8.346)	8.83 (9.440)
Median	5.65	4.14	5.22
Q1, Q3	2.76, 19.22	1.58, 8.77	2.53, 10.25
Min, Max	0.7, 30.1	0.7, 30.3	0.7, 30.3
Duration of Treatment, n (%)			
< 1 month	2 (15.4)	2 (11.8)	4 (13.3)
≥ 1 to < 3 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 3 to < 6 months	3 (23.1)	4 (23.5)	7 (23.3)
≥ 6 to < 12 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 12 to < 18 months	0 (0.0)	0 (0.0)	0 (0.0)
≥ 18 to < 24 months	1 (7.7)	2 (11.8)	3 (10.0)
≥ 24 months	3 (23.1)	1 (5.9)	4 (13.3)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Number of Cycles Received			
n	13	17	30
Mean (SD)	14.5 (14.54)	9.2 (10.30)	11.5 (12.38)
Median	8.0	5.0	7.5
Q1, Q3	4.0, 28.0	2.0, 12.0	3.0, 14.0
Min, Max	1, 41	1, 39	1, 41
Number of Cycles Received, n (%)			
1-3	3 (23.1)	7 (41.2)	10 (33.3)
4-6	1 (7.7)	3 (17.6)	4 (13.3)
7-9	4 (30.8)	1 (5.9)	5 (16.7)
10-12	1 (7.7)	2 (11.8)	3 (10.0)
13-18	0 (0.0)	2 (11.8)	2 (6.7)
19-24	0 (0.0)	0 (0.0)	0 (0.0)
25-36	3 (23.1)	1 (5.9)	4 (13.3)
>36	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Cumulative Total Dose (mg) per Patient [b]			
n	13	17	30
Mean (SD)	2907.69 (2908.167)	1835.29 (2059.412)	2300.00 (2476.232)
Median	1600.00	1000.00	1500.00
Q1, Q3	800.00, 5600.00	400.00, 2400.00	600.00, 2800.00
Min, Max	200.0, 8200.0	200.0, 7800.0	200.0, 8200.0
Actual Dose Intensity (mg/cycle) per Patient [c]			
n	13	17	30
Mean (SD)	189.00 (15.516)	177.94 (26.280)	182.73 (22.621)
Median	195.68	186.67	191.66
Q1, Q3	187.50, 200.00	171.43, 198.11	171.43, 200.00
Min, Max	161.5, 200.3	112.4, 200.0	112.4, 200.3

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Relative Dose Intensity (%) per Patient [d]			
n	13	17	30
Mean (SD)	94.50 (7.758)	88.97 (13.140)	91.37 (11.310)
Median	97.84	93.33	95.83
Q1, Q3	93.75, 100.00	85.71, 99.06	85.71, 100.00
Min, Max	80.8, 100.2	56.2, 100.0	56.2, 100.2
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:37 t-14-3-1-1-1-ex-tis-pop1-ia.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Patients with Any Dose Modification, n (%)	7 (53.8)	11 (64.7)	18 (60.0)
Dose Delay	7 (53.8)	11 (64.7)	18 (60.0)
Adverse Event	3 (23.1)	10 (58.8)	13 (43.3)
Other	5 (38.5)	4 (23.5)	9 (30.0)
Related to COVID-19	1 (7.7)	2 (11.8)	3 (10.0)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	0 (0.0)	0 (0.0)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment (month) [a]				
n	13	13	17	17
Mean (SD)	4.12 (2.138)	6.20 (7.490)	3.51 (1.918)	4.88 (4.463)
Median	4.27	4.30	3.48	4.17
Q1, Q3	2.76, 4.90	2.79, 6.87	1.68, 4.40	1.71, 6.14
Min, Max	0.7, 8.3	0.7, 30.1	0.7, 7.2	0.7, 19.1

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment, n (%)				
< 1 month	2 (15.4)	2 (15.4)	2 (11.8)	2 (11.8)
≥ 1 to < 3 months	2 (15.4)	2 (15.4)	4 (23.5)	4 (23.5)
≥ 3 to < 6 months	7 (53.8)	5 (38.5)	9 (52.9)	6 (35.3)
≥ 6 to < 12 months	2 (15.4)	3 (23.1)	2 (11.8)	4 (23.5)
≥ 12 to ≤ 18 months	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
> 18 months	0 (0.0)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received				
n	13	13	17	17
Mean (SD)	5.5 (2.67)	7.9 (8.87)	4.5 (2.45)	5.9 (4.40)
Median	6.0	6.0	5.0	5.0
Q1, Q3	4.0, 6.0	4.0, 8.0	2.0, 6.0	2.0, 8.0
Min, Max	1, 10	1, 36	1, 9	1, 16

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received, n (%)				
1-3	3 (23.1)	3 (23.1)	7 (41.2)	7 (41.2)
4-6	7 (53.8)	5 (38.5)	7 (41.2)	4 (23.5)
7-9	2 (15.4)	3 (23.1)	3 (17.6)	3 (17.6)
10-12	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)
13-18	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
>18	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Cumulative Total Dose (mg/m^2) per Patient [b]				
n	13	13	17	17
Mean (SD)	356.59 (173.633)	30964.21 (36550.245)	289.96 (155.327)	21330.62 (16827.808)
Median	359.07	22461.80	296.93	19909.72
Q1, Q3	276.36, 451.08	16162.38, 31793.25	164.68, 402.36	8162.99, 26944.39
Min, Max	71.9, 648.8	3671.0, 147393.0	59.9, 556.6	3749.5, 63186.2

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Actual Dose Intensity (mg/m^2/cycle) per Patient [c]				
n	13	13	17	17
Mean (SD)	62.39 (12.288)	3510.98 (364.760)	59.38 (12.483)	3176.21 (630.213)
Median	59.84	3504.12	58.30	3485.46
Q1, Q3	53.85, 73.42	3321.09, 3712.21	50.12, 67.03	2710.97, 3665.54
Min, Max	38.2, 80.6	2695.7, 3993.1	41.3, 82.3	2171.8, 3986.6

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Relative Dose Intensity (%) per Patient [d]				
n	13	13	17	17
Mean (SD)	87.64 (16.755)	90.49 (9.807)	82.39 (16.600)	79.92 (16.241)
Median	96.97	93.44	84.41	78.65
Q1, Q3	84.77, 99.22	83.86, 98.68	68.89, 97.17	67.77, 95.44
Min, Max	47.7, 100.7	67.4, 99.8	54.2, 102.9	54.3, 99.7
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	0 (0.0)	1 (5.9)	2 (11.8)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Patients with Any Dose Modification, n (%)	7 (53.8)	8 (61.5)	12 (70.6)	14 (82.4)
Dose Delay	7 (53.8)	7 (53.8)	9 (52.9)	10 (58.8)
Adverse Event	5 (38.5)	4 (30.8)	8 (47.1)	8 (47.1)
Other	3 (23.1)	4 (30.8)	1 (5.9)	3 (17.6)
Related to COVID-19	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	3 (23.1)	0 (0.0)	7 (41.2)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
Other	0 (0.0)	3 (23.1)	0 (0.0)	6 (35.3)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.
[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.
[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.
[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-chemo.sas 14NOV2024 00:36 t-14-3-1-1-2-ex-chemo-a-pop1-ia.rtf

Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Dose Reduction	4 (30.8)	2 (15.4)	11 (64.7)	8 (47.1)
Adverse Event	4 (30.8)	2 (15.4)	9 (52.9)	8 (47.1)
Other	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-chemo.sas 14NOV2024 00:36 t-14-3-1-1-2-ex-chemo-a-pop1-ia.rtf

Table 14.3.1.2.1.1:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	13	13 (100.0)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.1)	0.420 (0.145, 1.218)	0.1047
TEAE >= Grade 3	13	10 (76.9)	0.9 (0.2, 7.1)	17	14 (82.4)	1.0 (0.2, 2.1)	0.936 (0.313, 2.795)	0.9373
Serious TEAE	13	4 (30.8)	NR (5.0, NE)	17	6 (35.3)	20.5 (0.3, NE)	1.033 (0.245, 4.359)	0.9650
TEAE Leading to Treatment Discontinuation	13	2 (15.4)	NR (NE, NE)	17	6 (35.3)	NR (3.9, NE)	1.071 (0.177, 6.472)	0.9406

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

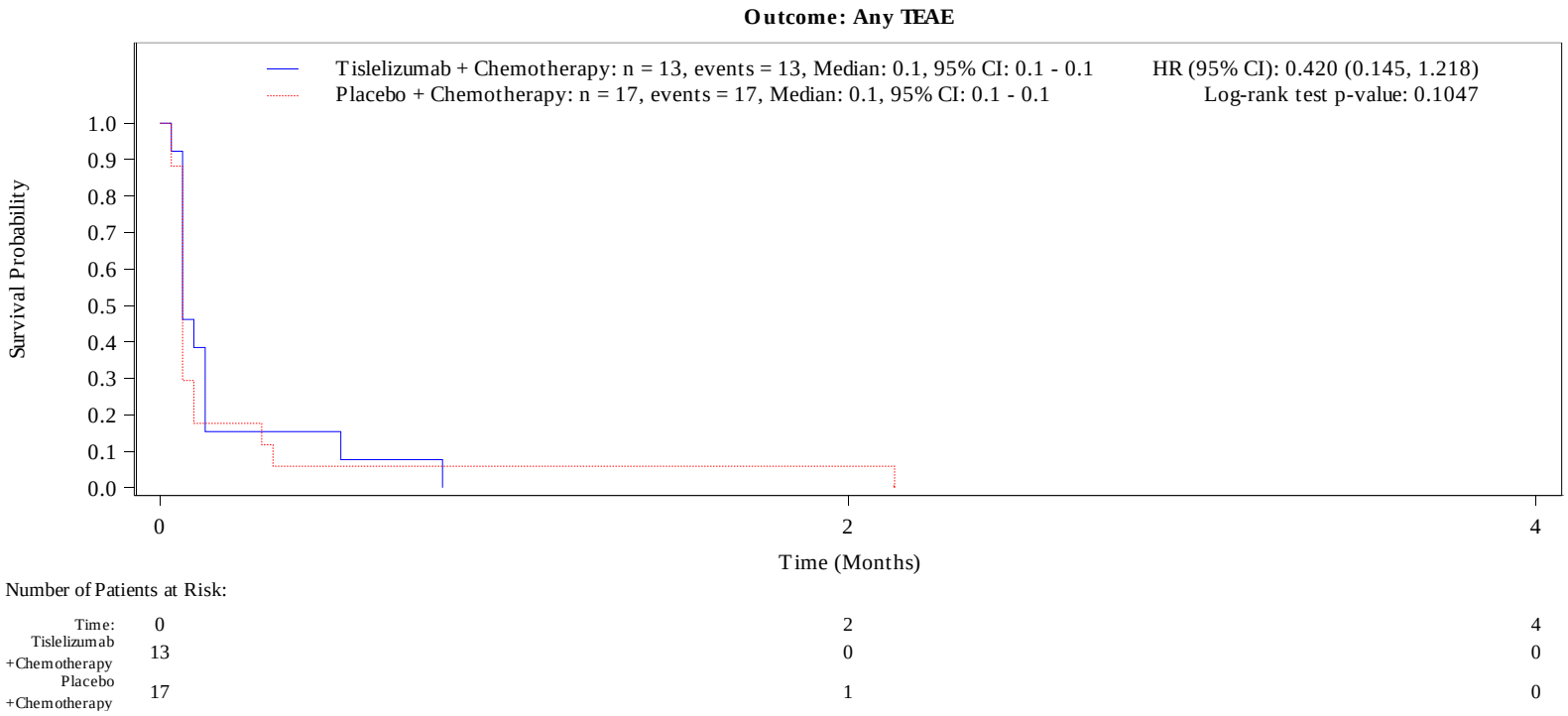
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

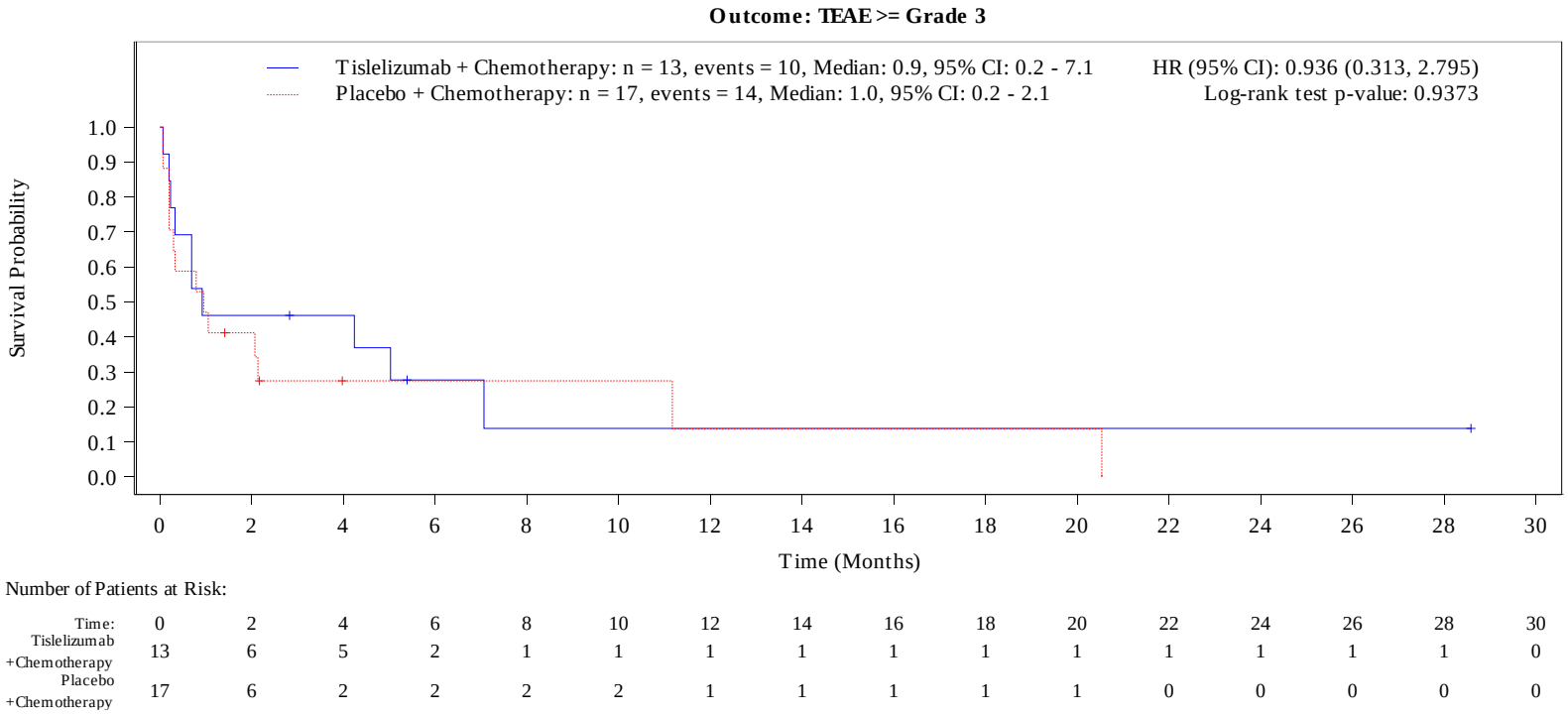
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-tte-aesum.sas 21OCT2024 09:17 t-14-3-1-2-1-1-tte-aesum-pop1-ia.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



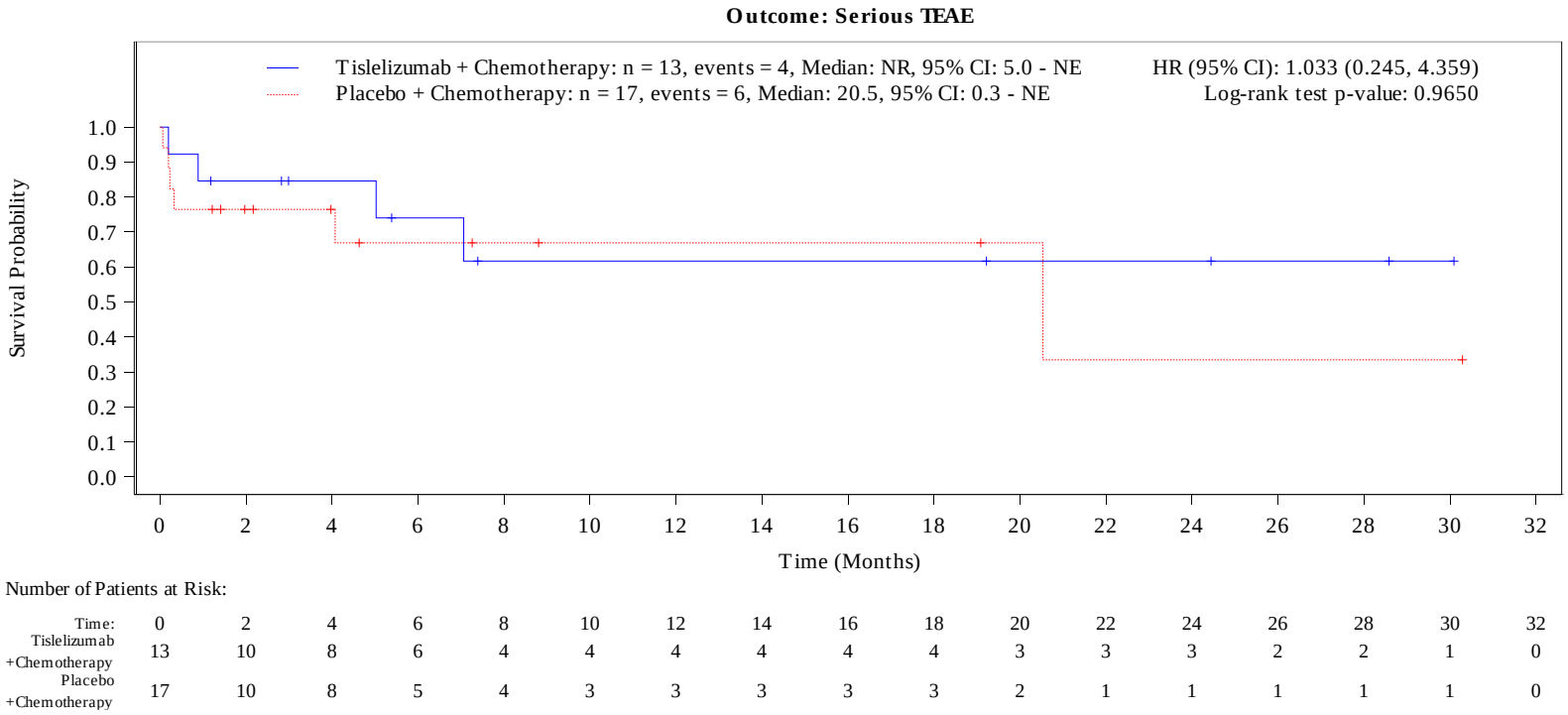
Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-ia.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



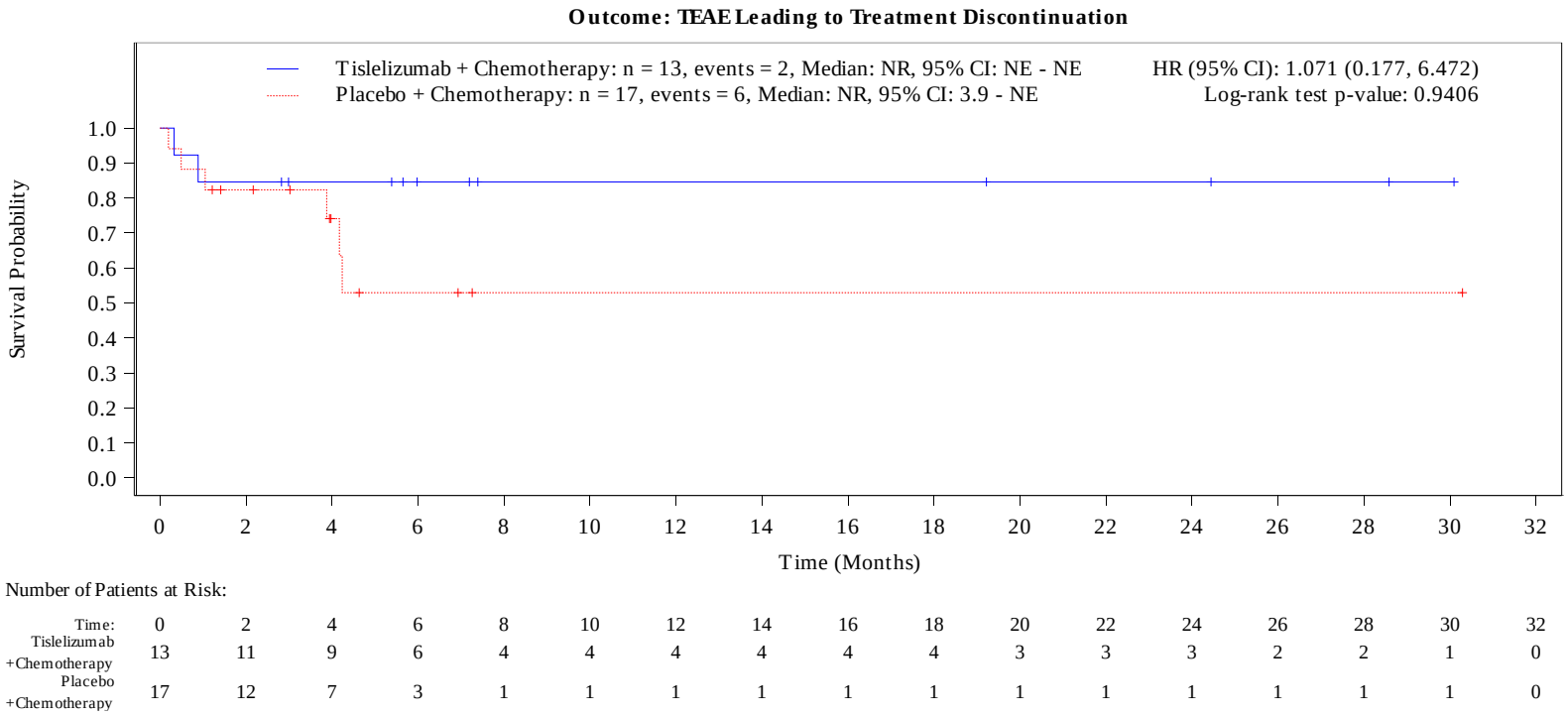
Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-ia.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-ia.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	3	3	3	2	2	1	0
Placebo +Chemotherapy	17	12	7	3	1	1	1	1	1	1	1	1	1	1	1	1	0

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-ia.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	9 (100.0)	0.1 (0.0, 0.5)	8	8 (100.0)	0.1 (0.0, 0.3)	0.890 (0.323, 2.454)	0.9808
Age >= 65	4	4 (100.0)	0.1 (0.1, NE)	9	9 (100.0)	0.1 (0.0, 0.1)	1.052 (0.294, 3.762)	0.9825
Interaction								0.8740

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	9 (100.0)	0.1 (0.1, 0.1)	11	11 (100.0)	0.1 (0.0, 0.1)	0.700 (0.275, 1.782)	0.3126
Female	4	4 (100.0)	0.1 (0.0, NE)	6	6 (100.0)	0.1 (0.1, NE)	0.971 (0.244, 3.866)	0.6939
Interaction								0.7957

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	7 (100.0)	0.1 (0.1, 0.1)	10	10 (100.0)	0.1 (0.0, 0.1)	0.275 (0.076, 0.991)	0.0233
1	6	6 (100.0)	0.1 (0.0, NE)	7	7 (100.0)	0.1 (0.1, 0.3)	1.474 (0.465, 4.673)	0.4652
Interaction								0.0384

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-tteae-subgrp.sas 21OCT2024 09:21 t-14-3-1-2-1-1-s-tteae-subgrp-pop1-ia.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.1 (0.1, NE)	7	7 (100.0)	0.1 (0.0, 0.1)	0.468 (0.107, 2.057)	0.2016
No	9	9 (100.0)	0.1 (0.0, 0.5)	10	10 (100.0)	0.1 (0.1, 0.3)	0.986 (0.384, 2.530)	0.9089
Interaction								0.4597

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-tteae-subgrp.sas 21OCT2024 09:21 t-14-3-1-2-1-1-s-tteae-subgrp-pop1-ia.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	6 (66.7)	4.2 (0.1, NE)	8	6 (75.0)	2.1 (0.3, NE)	1.002 (0.318, 3.157)	0.9984
Age >= 65	4	4 (100.0)	0.7 (0.2, NE)	9	8 (88.9)	0.2 (0.1, 1.0)	0.586 (0.153, 2.239)	0.4168
Interaction								0.4084

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-tteae-subgrp.sas 21OCT2024 09:21 t-14-3-1-2-1-1-s-tteae-subgrp-pop1-ia.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	8 (88.9)	0.7 (0.2, NE)	11	9 (81.8)	1.0 (0.2, NE)	1.072 (0.397, 2.898)	0.8967
Female	4	2 (50.0)	4.2 (0.1, NE)	6	5 (83.3)	0.9 (0.1, NE)	0.445 (0.084, 2.365)	0.3195
Interaction								0.3981

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	0.7 (0.2, NE)	10	9 (90.0)	0.9 (0.1, 2.1)	0.887 (0.304, 2.593)	0.8329
1	6	4 (66.7)	2.6 (0.1, NE)	7	5 (71.4)	1.0 (0.1, NE)	0.831 (0.217, 3.183)	0.7833
Interaction								0.9489

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.5 (0.1, NE)	7	6 (85.7)	0.8 (0.1, NE)	1.481 (0.387, 5.667)	0.5460
No	9	6 (66.7)	4.2 (0.2, NE)	10	8 (80.0)	1.6 (0.2, NE)	0.654 (0.222, 1.924)	0.4392
Interaction								0.4606

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	3 (33.3)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	1 (14.3)	--	--	--
No	9	1 (11.1)	--	10	5 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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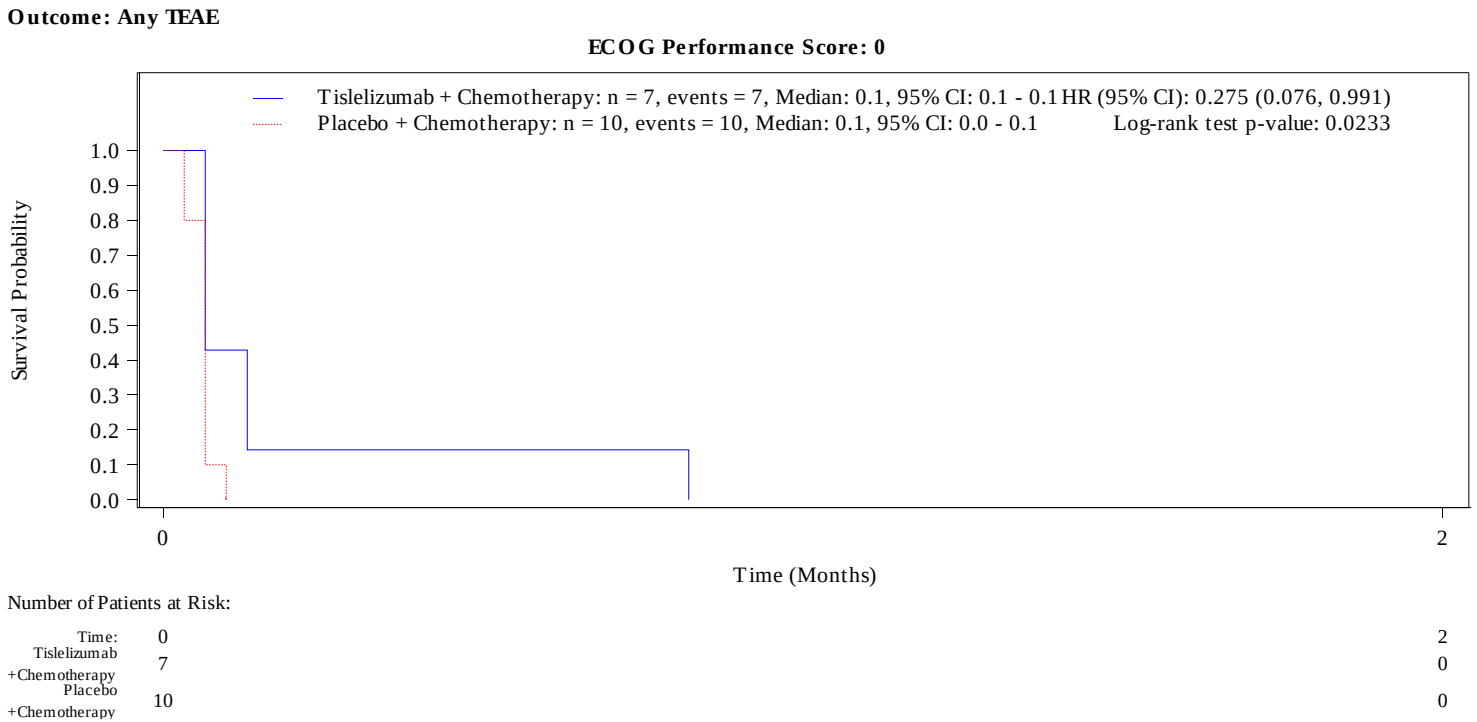
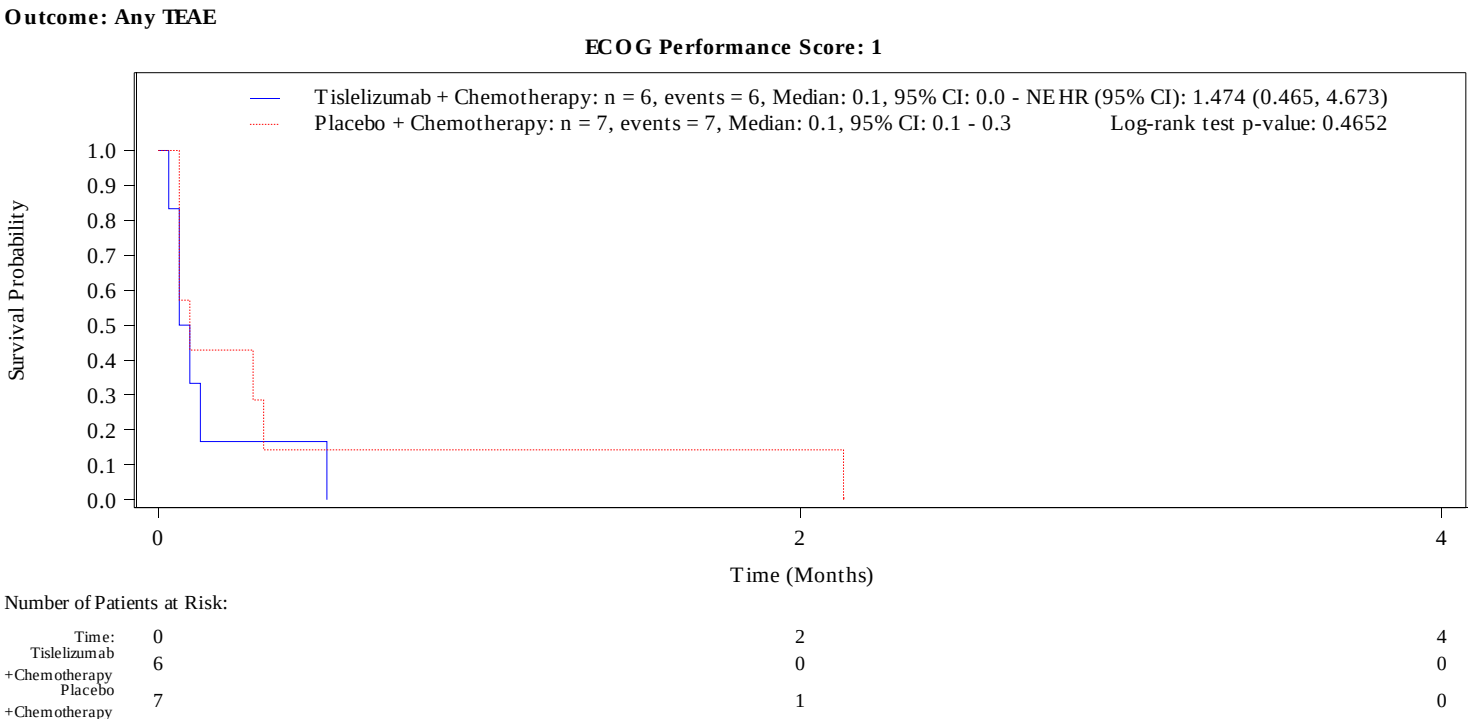
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	8 (61.5)	1.4 (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	4.057 (0.957, 17.200)	0.0451
Anaemia	13	6 (46.2)	NR (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	3.407 (0.772, 15.033)	0.0923
Leukopenia	13	2 (15.4)	NR (1.3, NE)	17	1 (5.9)	NR (NE, NE)	2.442 (0.202, 29.535)	0.4712
Neutropenia	13	3 (23.1)	NR (1.4, NE)	17	3 (17.6)	NR (5.0, NE)	2.435 (0.367, 16.158)	0.3451
Endocrine disorders	13	2 (15.4)	NR (4.2, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3008
Gastrointestinal disorders	13	11 (84.6)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.2)	1.027 (0.408, 2.589)	0.9873

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Constipation	13	8 (61.5)	0.8 (0.1, NE)	17	9 (52.9)	0.9 (0.1, NE)	0.606 (0.201, 1.833)	0.4122
Diarrhoea	13	3 (23.1)	NR (3.5, NE)	17	7 (41.2)	15.7 (0.8, NE)	1.092 (0.216, 5.529)	0.9152
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	20.5 (20.5, NE)	NE (NE, NE)	NE
Nausea	13	5 (38.5)	NR (0.1, NE)	17	9 (52.9)	0.8 (0.1, NE)	0.775 (0.237, 2.530)	0.6705
Stomatitis	13	5 (38.5)	NR (0.2, NE)	17	7 (41.2)	NR (0.4, NE)	1.091 (0.260, 4.580)	0.9449
General disorders and administration site conditions	13	7 (53.8)	1.7 (0.1, NE)	17	12 (70.6)	0.2 (0.1, NE)	0.588 (0.216, 1.600)	0.3153

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Asthenia	13	1 (7.7)	NR (NE, NE)	17	4 (23.5)	NR (1.2, NE)	0.592 (0.062, 5.654)	0.6573
Fatigue	13	2 (15.4)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.493 (0.078, 3.128)	0.4453
Generalised oedema	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Malaise	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.345 (0.034, 3.496)	0.3486
Pyrexia	13	2 (15.4)	NR (3.9, NE)	17	4 (23.5)	NR (12.3, NE)	1.204 (0.161, 8.988)	0.8560
Infections and infestations	13	5 (38.5)	9.4 (1.5, NE)	17	5 (29.4)	17.5 (7.2, NE)	3.558 (0.574, 22.063)	0.1560

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia	13	2 (15.4)	NR (11.9, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urinary tract infection	13	1 (7.7)	NR (3.3, NE)	17	2 (11.8)	NR (15.1, NE)	>999.99 (0.000, NE)	0.4497
Injury, poisoning and procedural complications	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336
Fall	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	13	10 (76.9)	0.7 (0.5, 4.2)	17	8 (47.1)	5.1 (0.5, NE)	1.161 (0.387, 3.481)	0.7769
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.243 (0.022, 2.711)	0.2283

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood creatinine increased	13	2 (15.4)	NR (1.4, NE)	17	2 (11.8)	NR (4.0, NE)	0.762 (0.100, 5.803)	0.7921
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.406 (0.089, 1.851)	0.2311
Platelet count decreased	13	4 (30.8)	NR (2.9, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0757
Weight decreased	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (5.1, NE)	0.712 (0.063, 8.022)	0.7822
White blood cell count decreased	13	4 (30.8)	NR (4.2, NE)	17	6 (35.3)	NR (1.6, NE)	0.204 (0.039, 1.080)	0.0415

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	13	9 (69.2)	1.8 (0.5, NE)	17	9 (52.9)	6.5 (0.5, NE)	1.352 (0.454, 4.025)	0.5963
Decreased appetite	13	6 (46.2)	6.7 (0.8, NE)	17	4 (23.5)	NR (6.7, NE)	2.575 (0.588, 11.282)	0.1983
Hyperglycaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1614
Hyperuricaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1086
Hypokalaemia	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.555 (0.056, 5.515)	0.6104
Hyponatraemia	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.614 (0.052, 7.308)	0.6974
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1614

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	14.6 (9.3, NE)	2.236 (0.111, 44.877)	0.5930
Nervous system disorders	13	2 (15.4)	NR (5.4, NE)	17	9 (52.9)	3.3 (0.3, NE)	0.211 (0.041, 1.086)	0.0461
Dysgeusia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Peripheral sensory neuropathy	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.3, NE)	0.700 (0.100, 4.925)	0.7195
Psychiatric disorders	13	2 (15.4)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Insomnia	13	1 (7.7)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072
Renal and urinary disorders	13	1 (7.7)	NR (4.7, NE)	17	5 (29.4)	NR (2.8, NE)	0.176 (0.019, 1.637)	0.0892
Chronic kidney disease	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Renal impairment	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.2, NE)	0.000 (0.000, NE)	0.0564
Respiratory, thoracic and mediastinal disorders	13	6 (46.2)	6.2 (1.1, NE)	17	8 (47.1)	2.4 (0.2, NE)	0.793 (0.248, 2.534)	0.7245
Cough	13	2 (15.4)	NR (16.5, NE)	17	1 (5.9)	NR (NE, NE)	1.768 (0.075, 41.454)	0.7221

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hiccups	13	2 (15.4)	NR (NE, NE)	17	4 (23.5)	NR (2.4, NE)	0.283 (0.049, 1.624)	0.1387
Skin and subcutaneous tissue disorders	13	6 (46.2)	6.9 (1.2, NE)	17	7 (41.2)	12.9 (1.2, NE)	0.932 (0.251, 3.464)	0.8956
Alopecia	13	2 (15.4)	NR (3.3, NE)	17	1 (5.9)	NR (NE, NE)	2.631 (0.211, 32.795)	0.4396
Palmar-plantar erythrodysaesthesia syndrome	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.6, NE)	0.000 (0.000, NE)	0.3173
Pruritus	13	3 (23.1)	26.7 (4.7, NE)	17	1 (5.9)	NR (12.9, NE)	>999.99 (0.000, NE)	0.4190
Rash	13	2 (15.4)	NR (6.9, NE)	17	1 (5.9)	NR (NE, NE)	1.699 (0.135, 21.378)	0.6790

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Vascular disorders	13	2 (15.4)	NR (5.4, NE)	17	4 (23.5)	NR (3.5, NE)	0.181 (0.019, 1.744)	0.1049
Flushing	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0673

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	2 (15.4)	NR (1.6, NE)	17	4 (23.5)	NR (4.0, NE)	0.819 (0.123, 5.460)	0.8364
Anaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.0, NE)	0.000 (0.000, NE)	0.0859
Leukopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Lymphopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Neutropenia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (5.0, NE)	0.000 (0.000, NE)	0.2008
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Eye disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859
Cataract	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	5 (29.4)	20.5 (1.1, NE)	0.424 (0.042, 4.291)	0.4580
Acquired soft palate fissure	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Diarrhoea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.630 (0.049, 8.140)	0.7214

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	13	2 (15.4)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0325
Asthenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Fatigue	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3173

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	13	2 (15.4)	NR (5.0, NE)	17	1 (5.9)	NR (NE, NE)	7.027 (0.614, 80.430)	0.0717
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Investigations	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.376 (0.084, 1.686)	0.1984
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4795
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	4 (23.5)	NR (2.1, NE)	0.844 (0.197, 3.605)	0.8183
White blood cell count decreased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.4, NE)	0.000 (0.000, NE)	0.1499
Metabolism and nutrition disorders	13	3 (23.1)	NR (1.8, NE)	17	5 (29.4)	11.2 (4.1, NE)	0.737 (0.126, 4.302)	0.7342
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	3.162 (0.184, 54.388)	0.4054
Hyperkalaemia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Hypoglycaemia	13	1 (7.7)	NR (17.2, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.1, NE)	0.000 (0.000, NE)	0.1439
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (11.2, NE)	0.000 (0.000, NE)	0.4795
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Skin and subcutaneous tissue disorders	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Rash	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	20.5 (20.5, NE)	0.821 (0.062, 10.940)	0.8814
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Nausea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Asthenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Infections and infestations	13	3 (23.1)	NR (1.5, NE)	17	1 (5.9)	NR (NE, NE)	7.889 (0.745, 83.509)	0.0530
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Pulmonary tuberculosis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Metabolism and nutrition disorders	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	1.000 (0.081, 12.270)	1.0000
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	0.000 (0.000, NE)	0.2253
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Nervous system disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Presyncope	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Patients with at Least One TEAE Leading to Any Treatment Discontinuation	2 (15.4)	6 (35.3)
General disorders and administration site conditions	1 (7.7)	0 (0.0)
Asthenia	1 (7.7)	0 (0.0)
Metabolism and nutrition disorders	1 (7.7)	0 (0.0)
Decreased appetite	1 (7.7)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (7.7)	0 (0.0)
Rash	1 (7.7)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	1 (5.9)
Acquired soft palate fissure	0 (0.0)	1 (5.9)

Source: ADSL, ADAE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.
Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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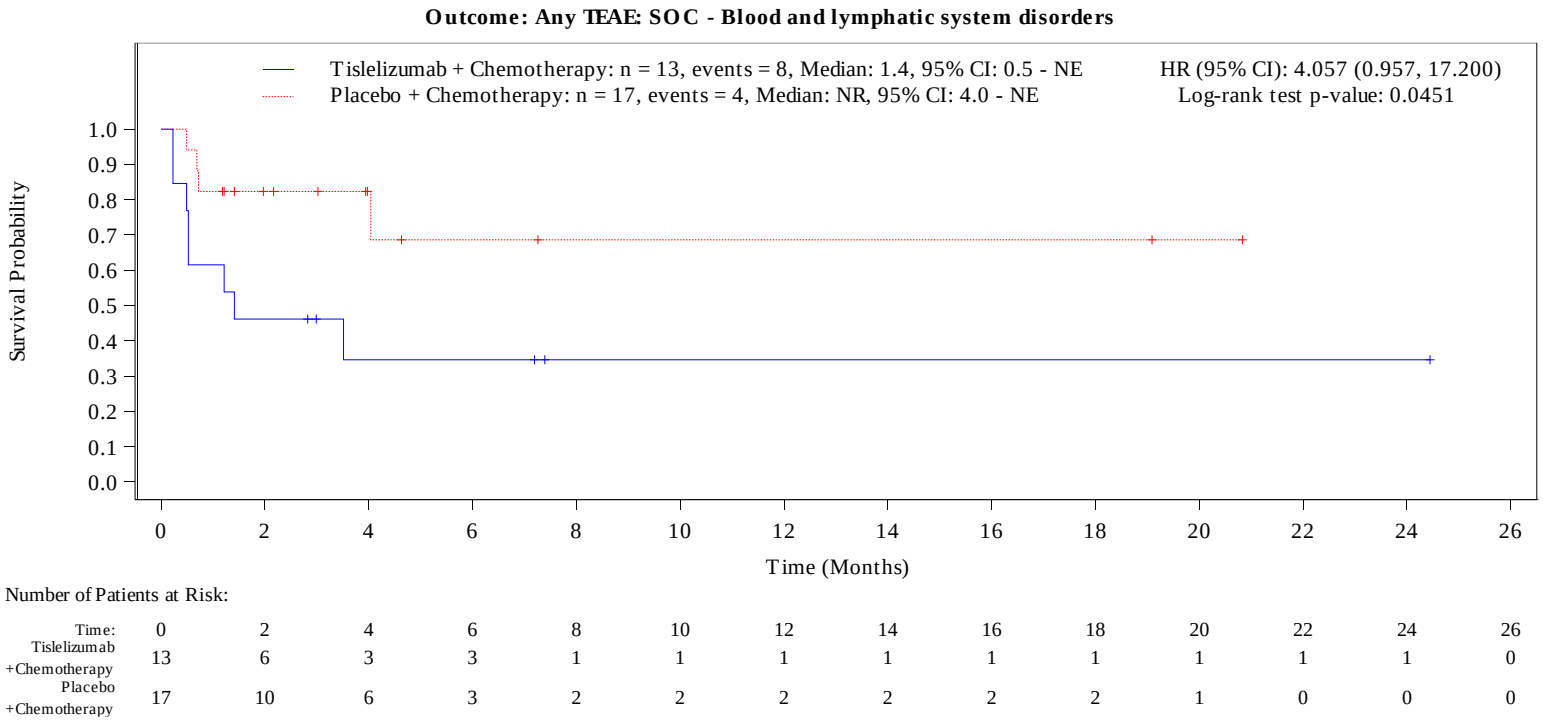
Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Infections and infestations	0 (0.0)	1 (5.9)
Pneumonia	0 (0.0)	1 (5.9)
Nervous system disorders	0 (0.0)	1 (5.9)
Peripheral sensory neuropathy	0 (0.0)	1 (5.9)
Renal and urinary disorders	0 (0.0)	3 (17.6)
Chronic kidney disease	0 (0.0)	1 (5.9)
Renal impairment	0 (0.0)	2 (11.8)

Source: ADSL, ADAE. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.
Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-socpt.sas 21OCT2024 08:37 t-14-3-1-5-1-socpt-dis-pop1-ia.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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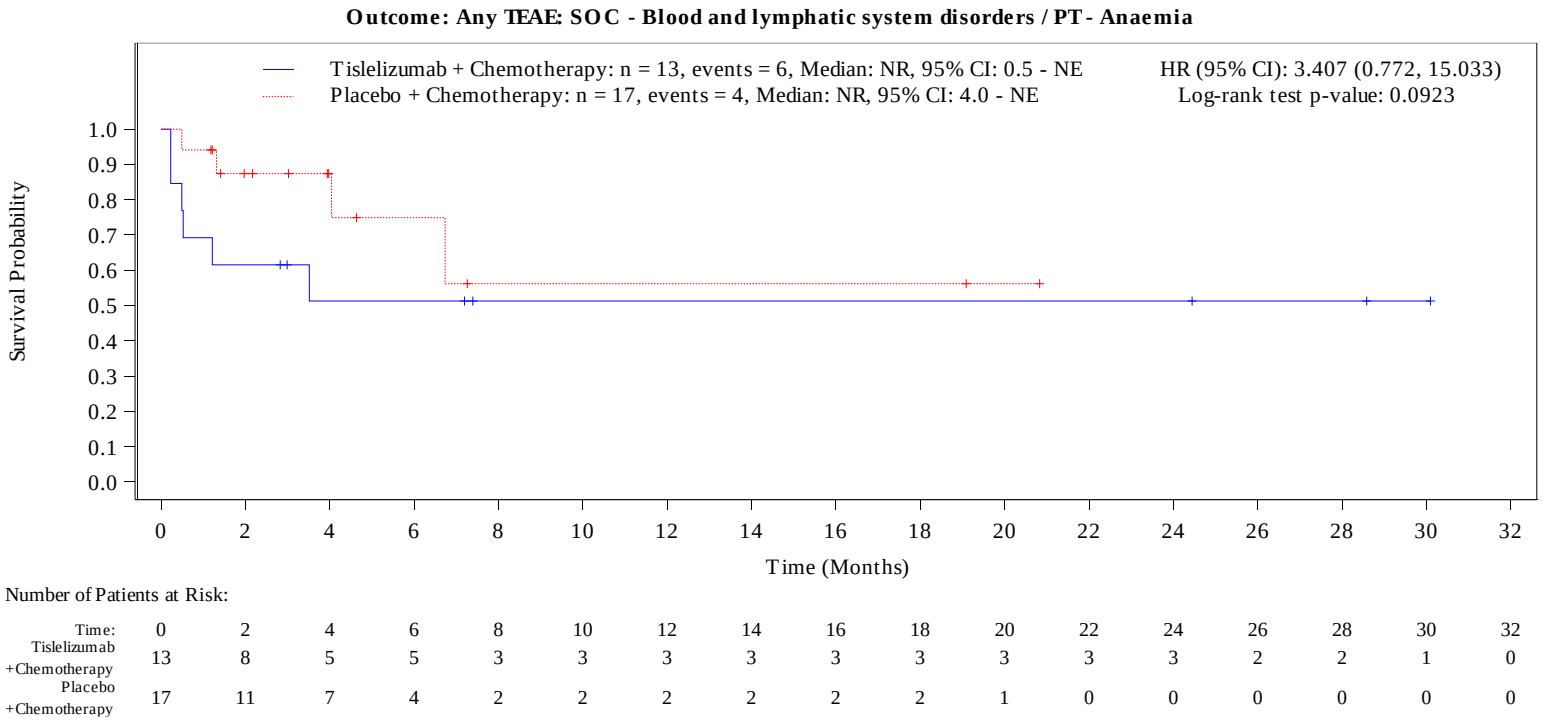
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab +Chemotherapy	13	8	5	5	3	3	3	3	3	3	3	3	3	2	2	1	0
Placebo +Chemotherapy	17	11	7	4	2	2	2	2	2	2	1	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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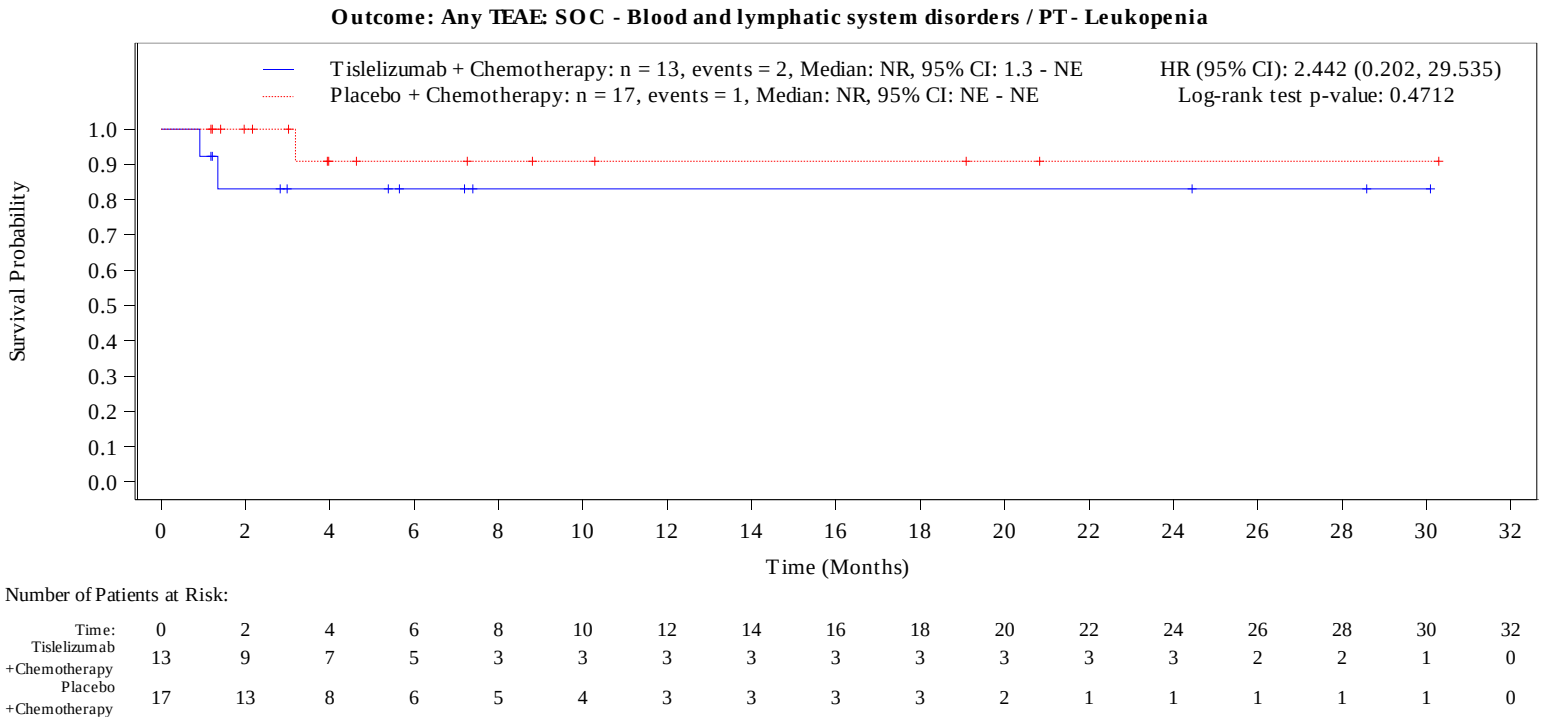
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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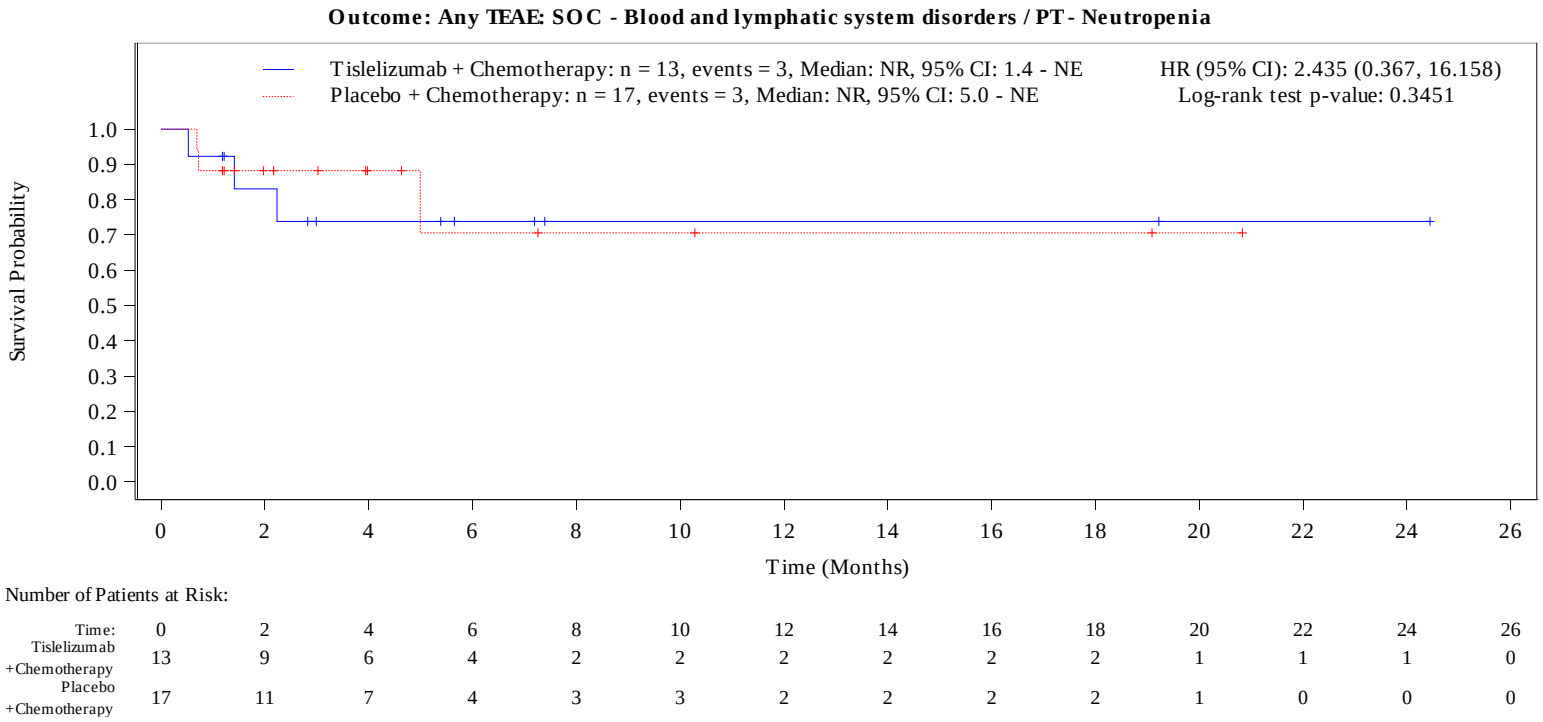
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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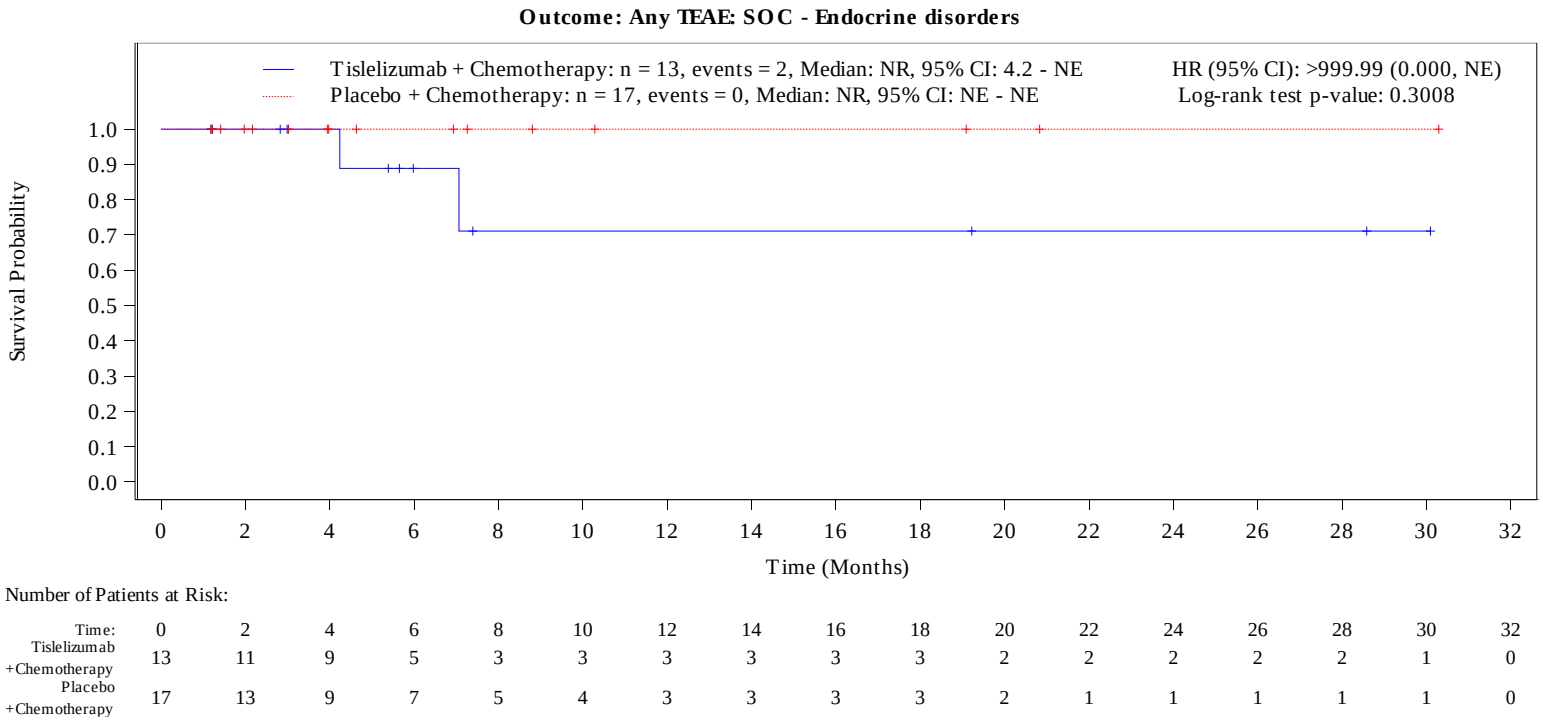
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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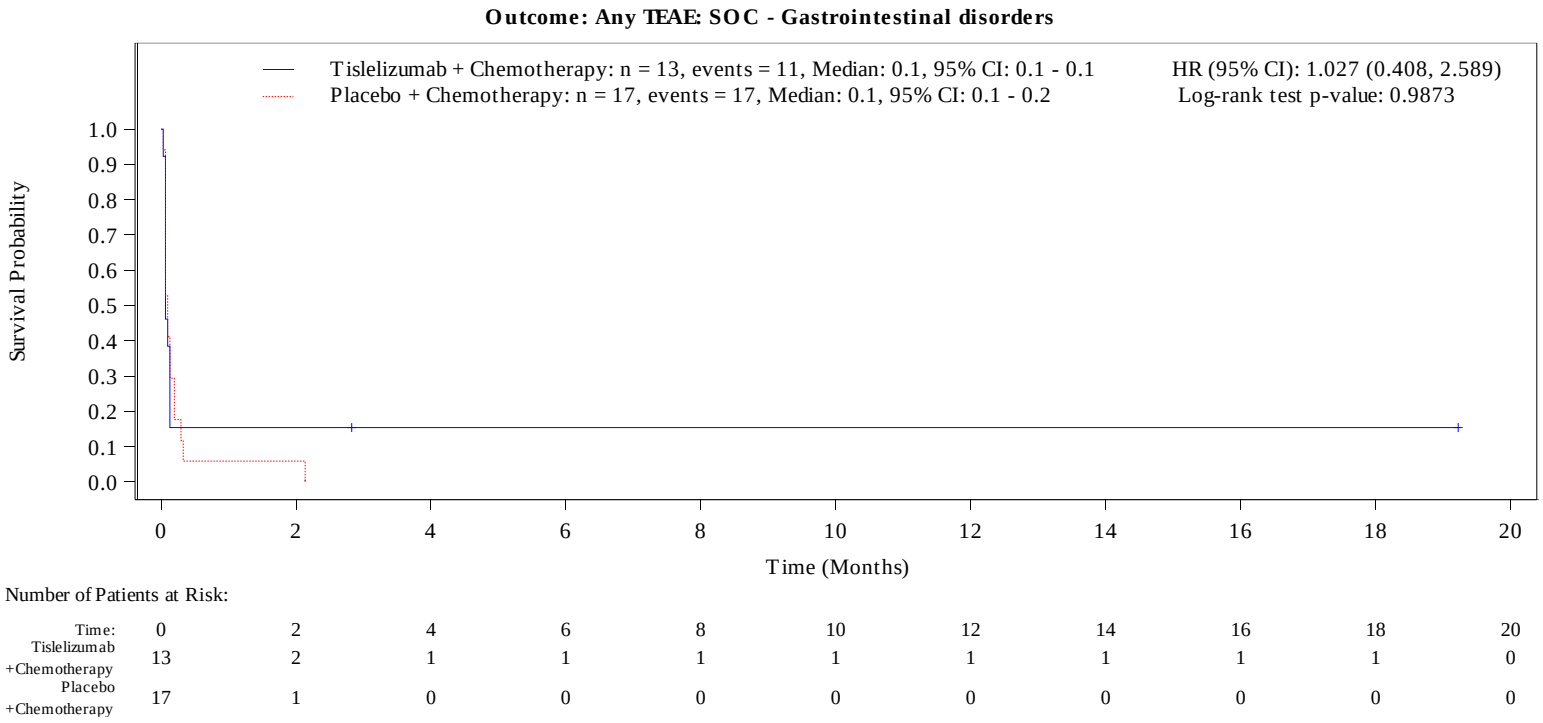

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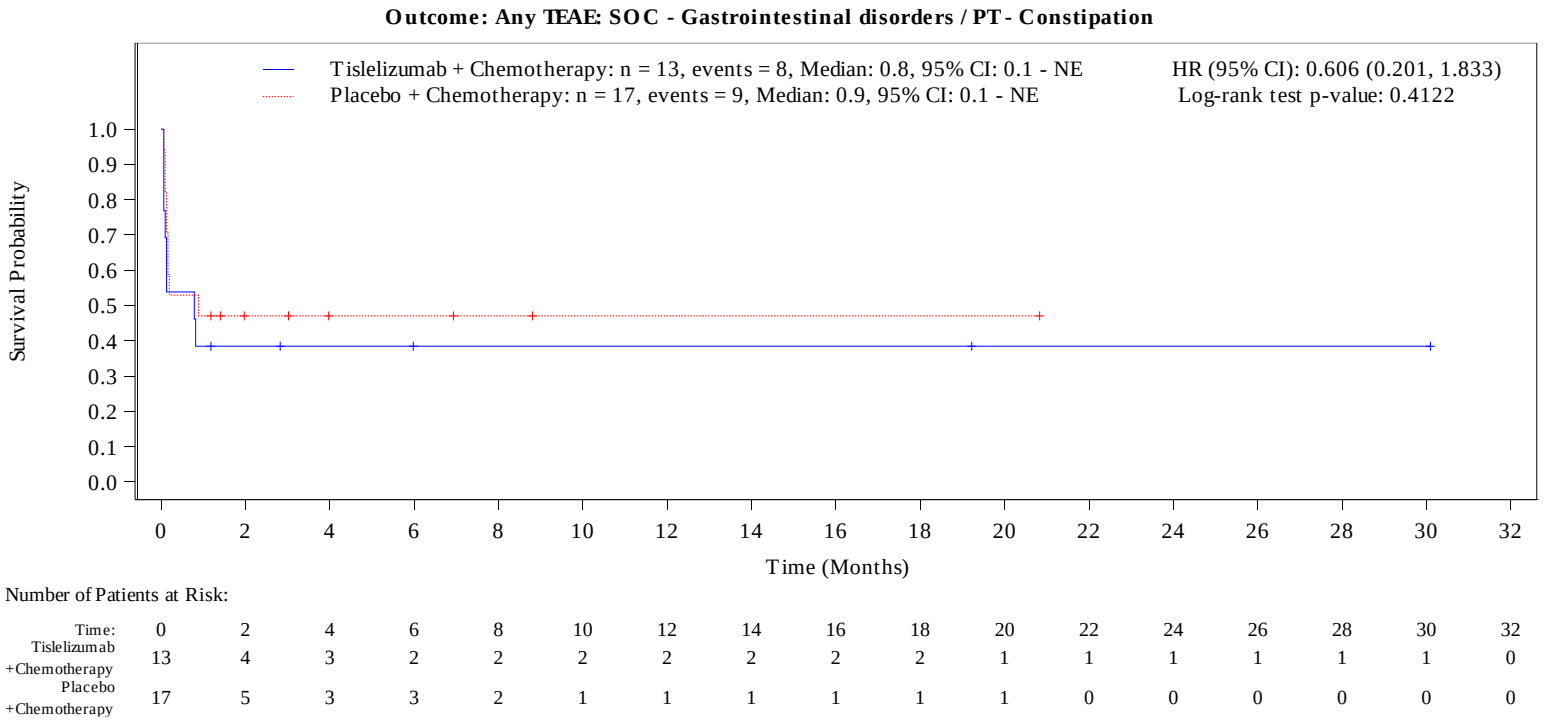

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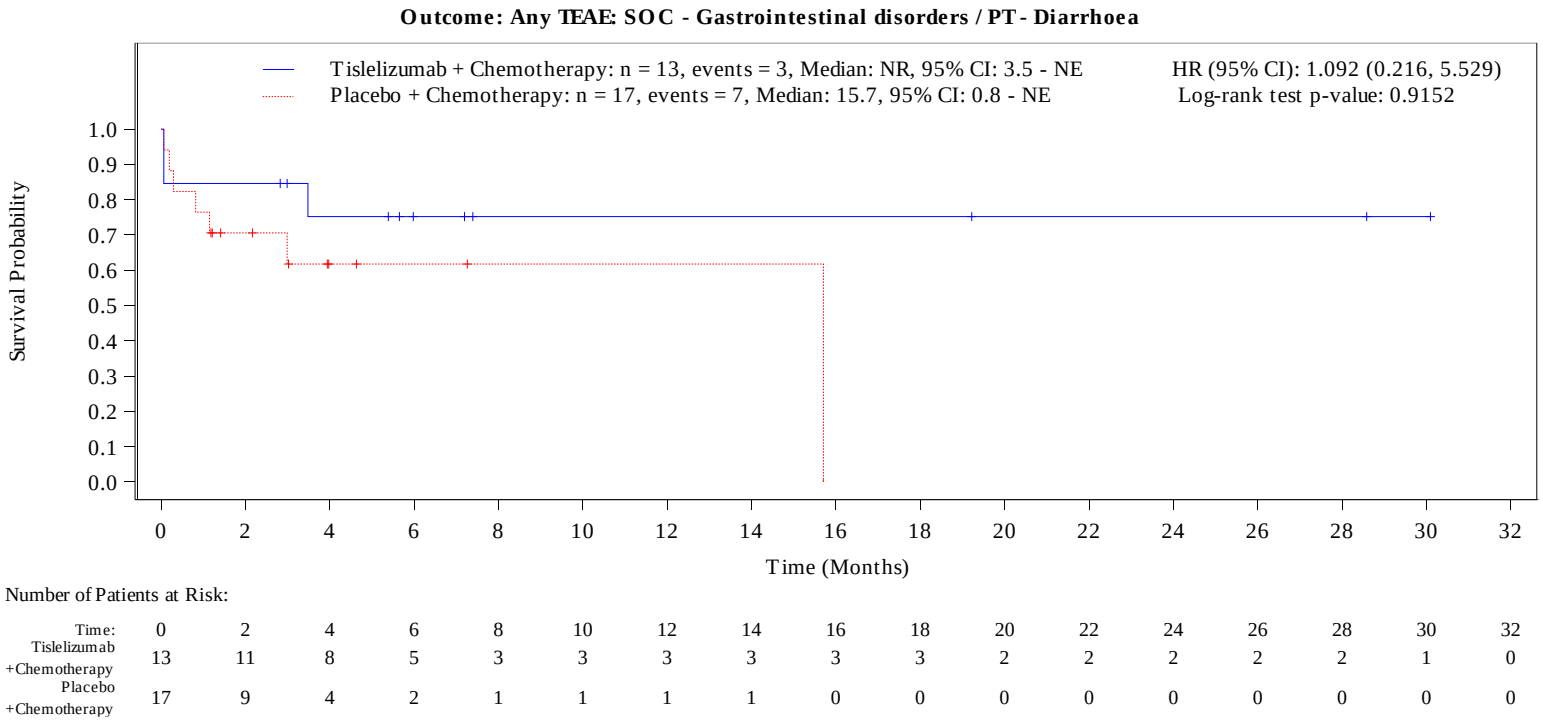

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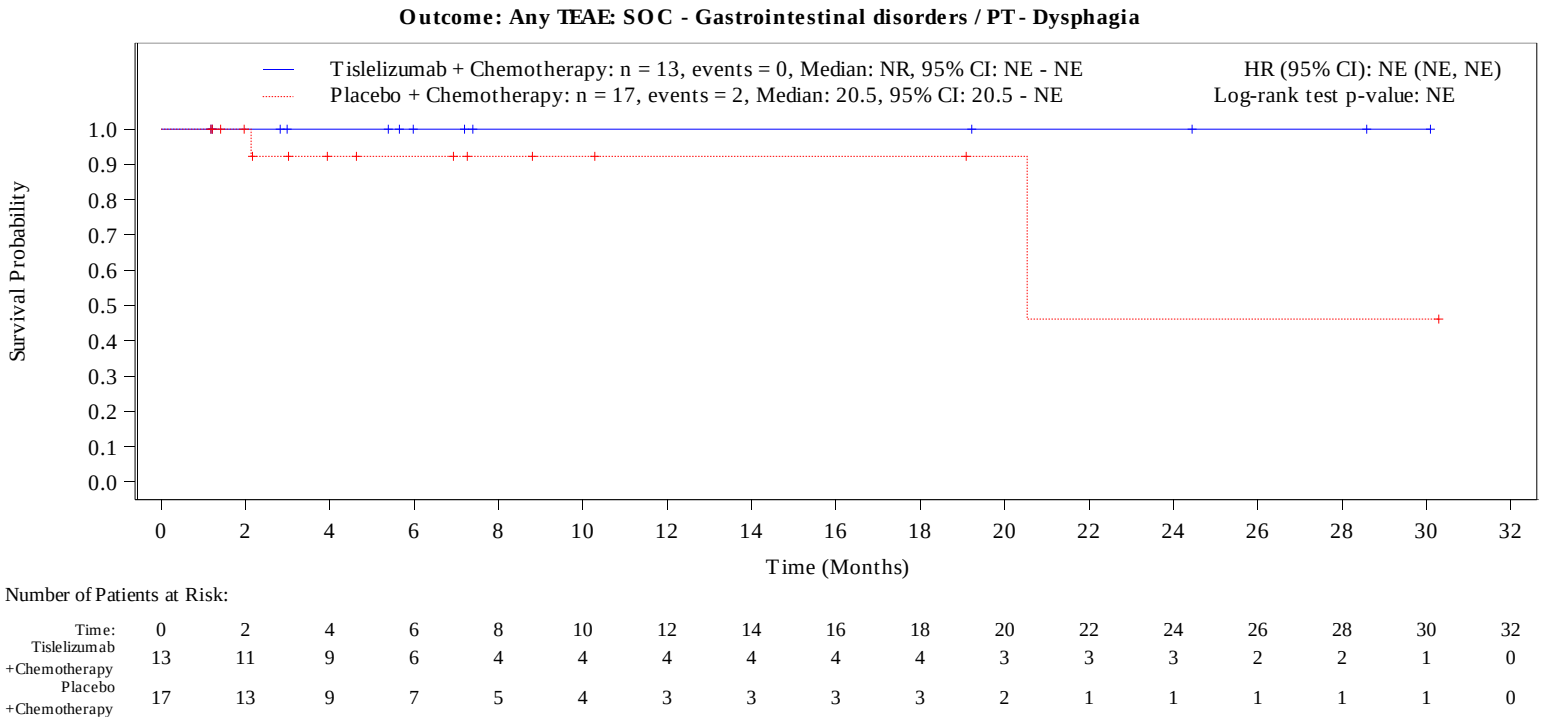

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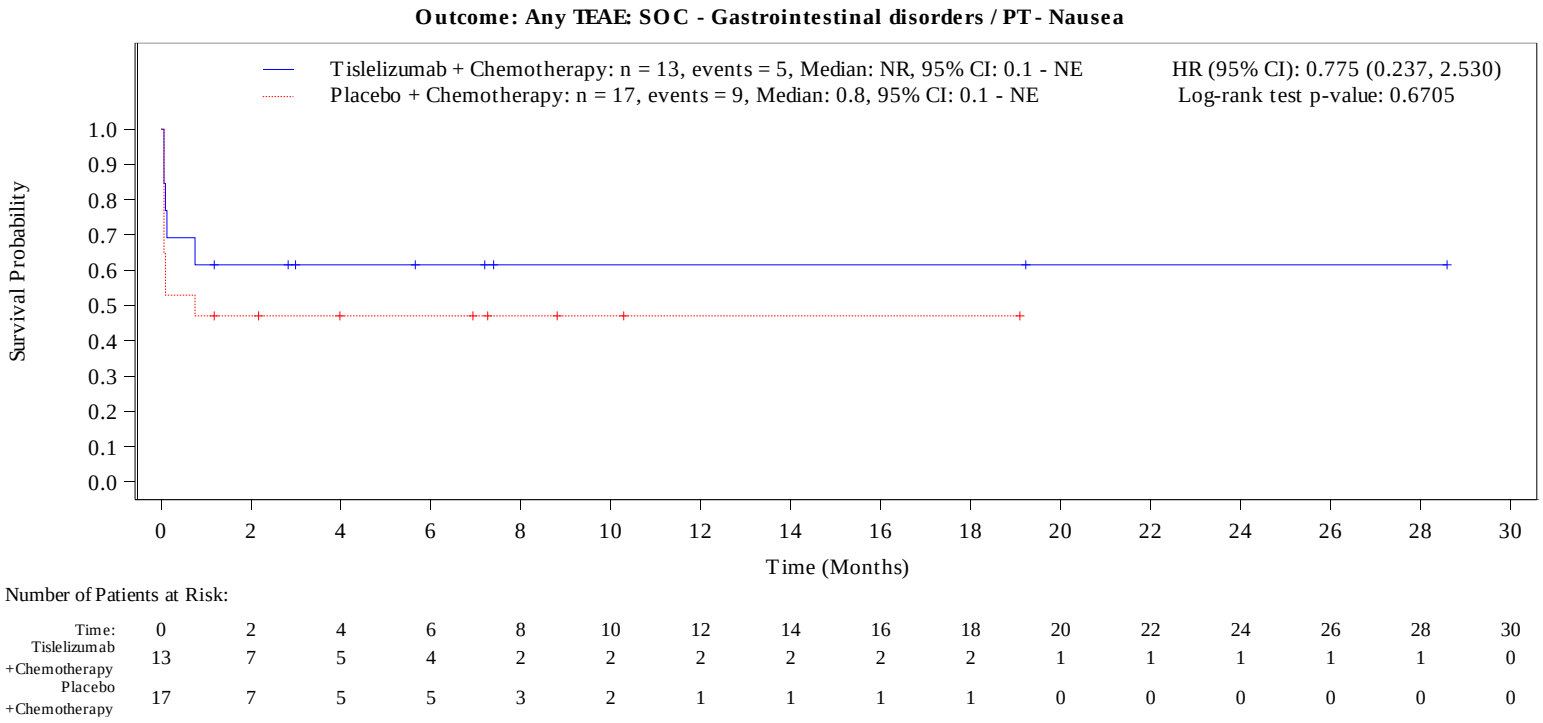

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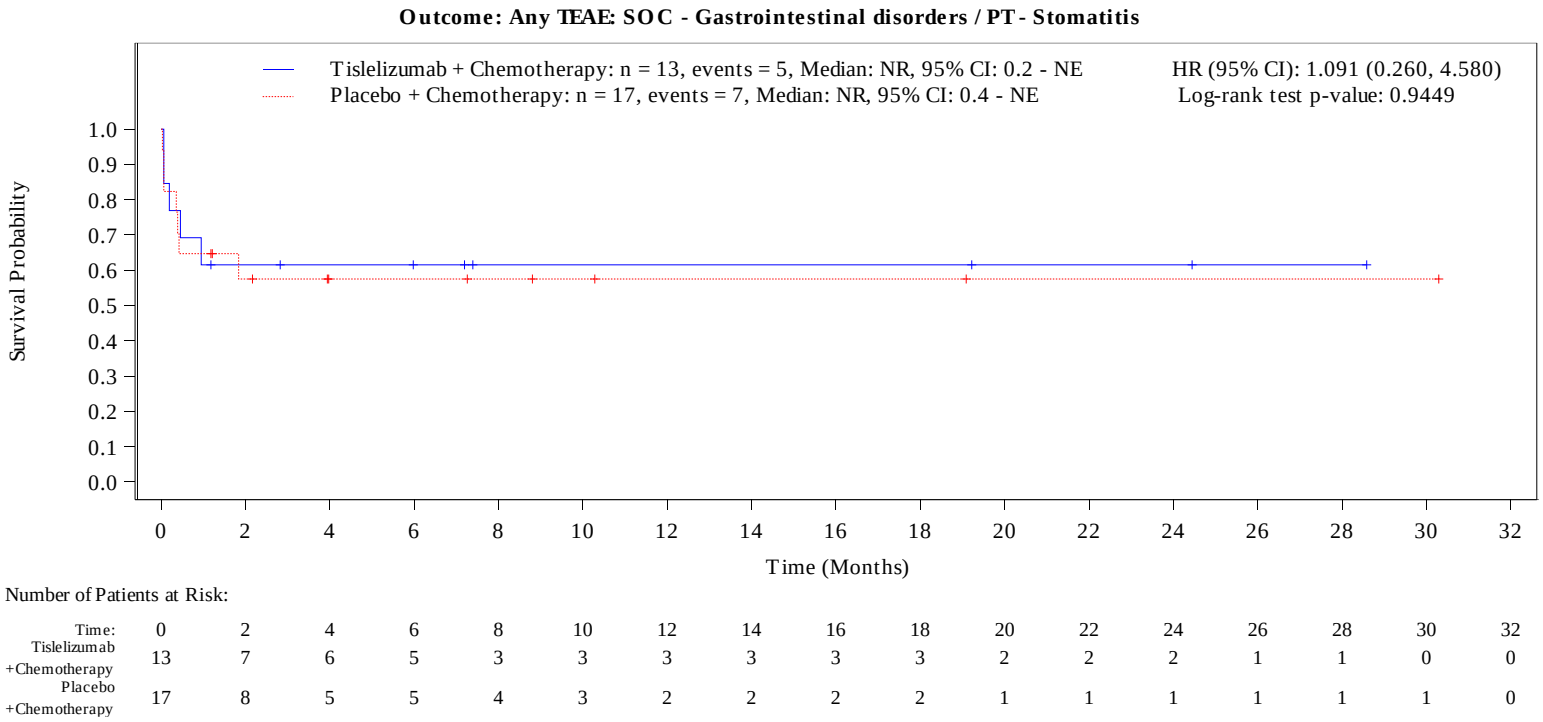

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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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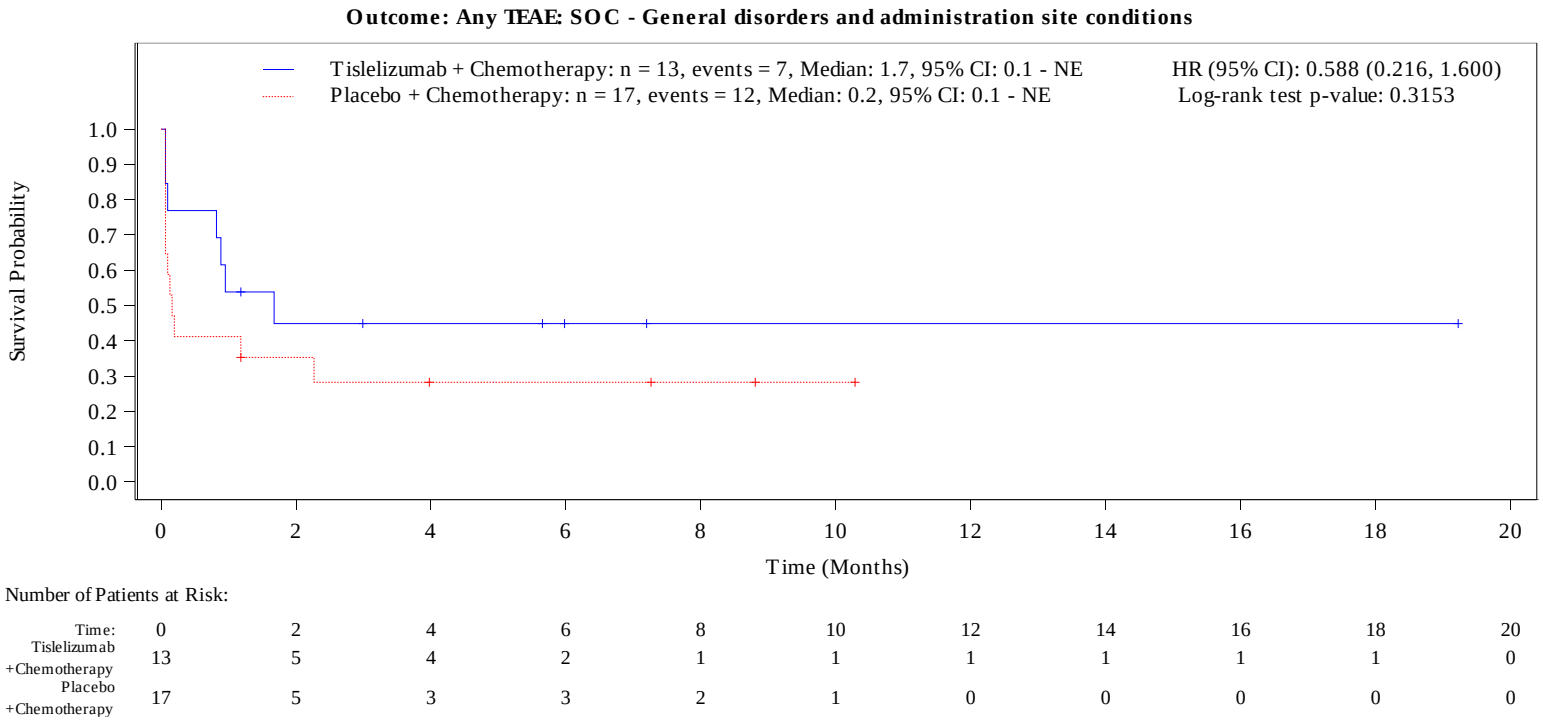
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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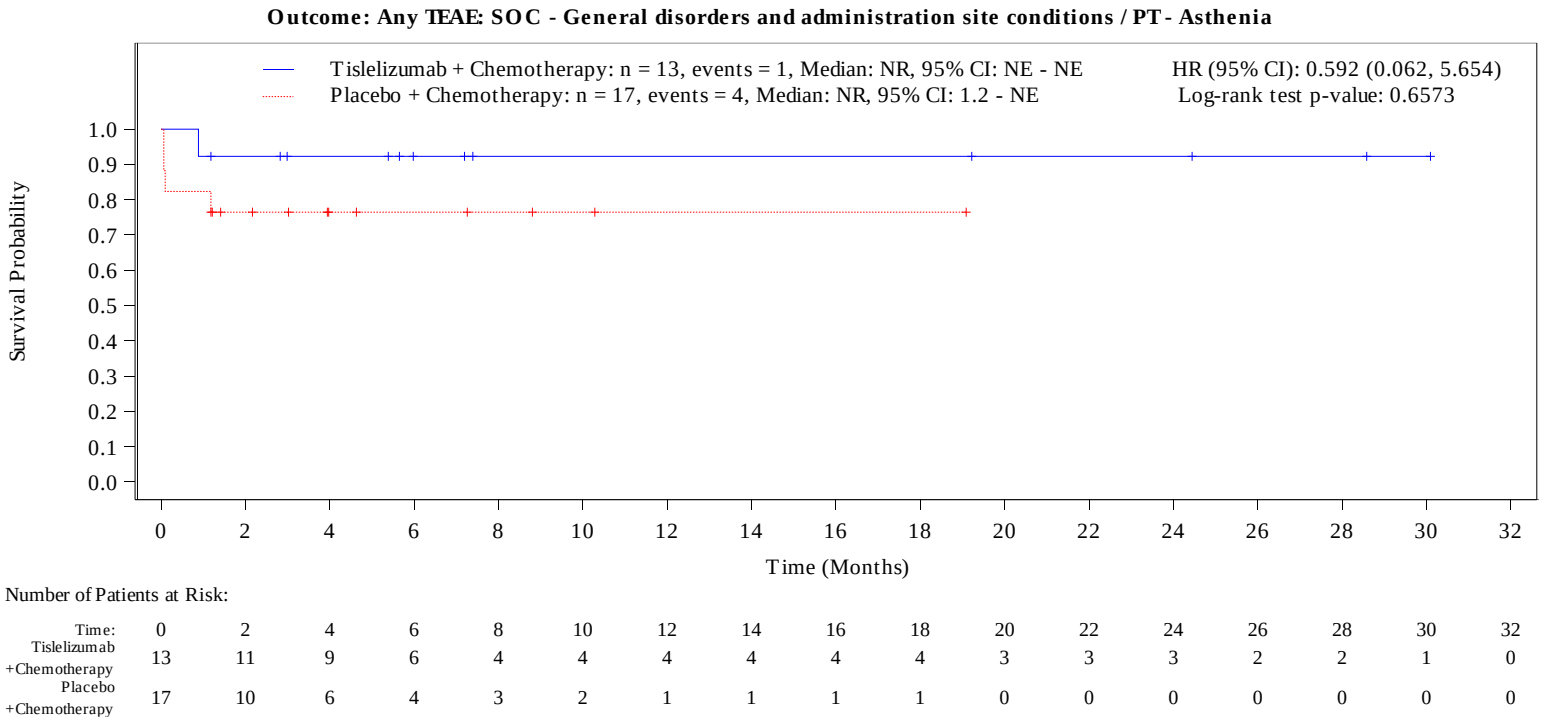

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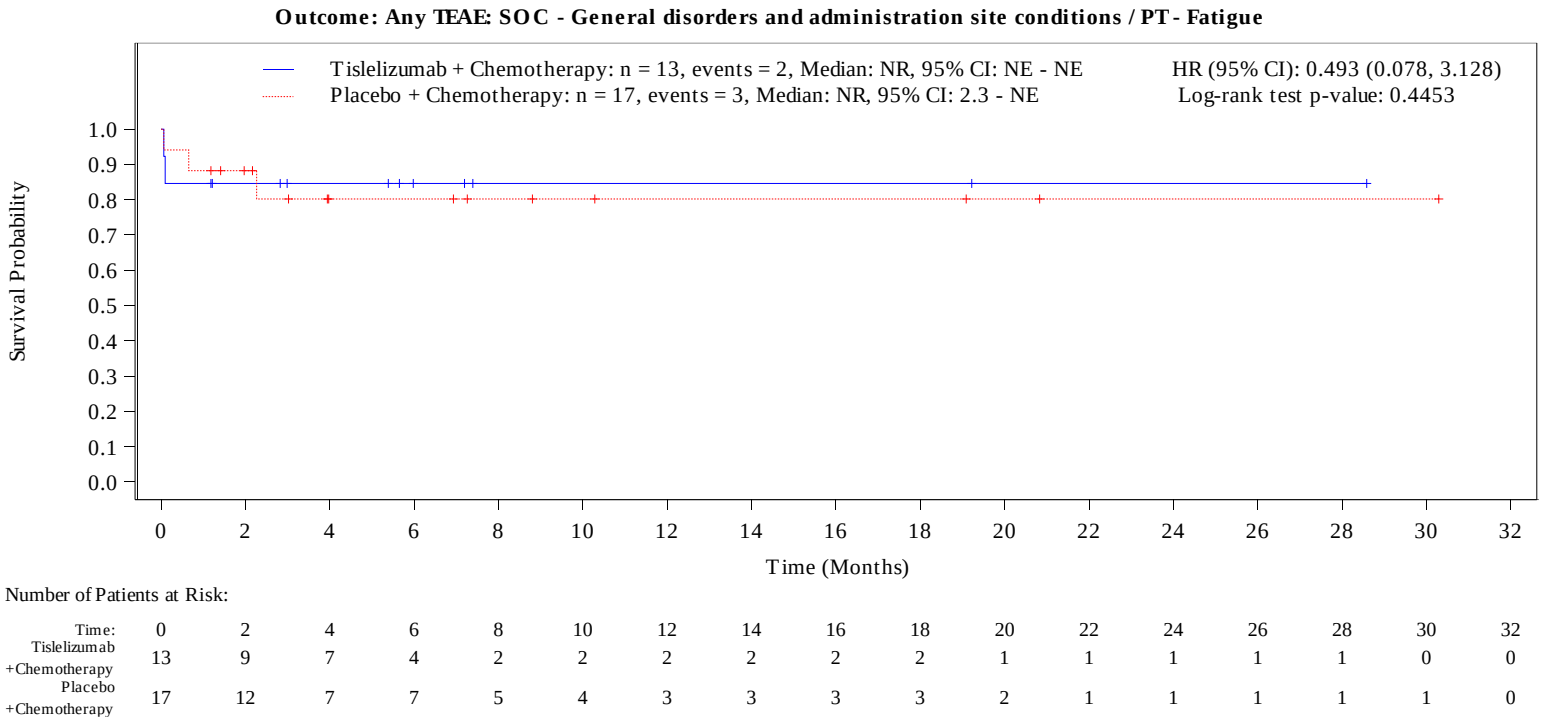

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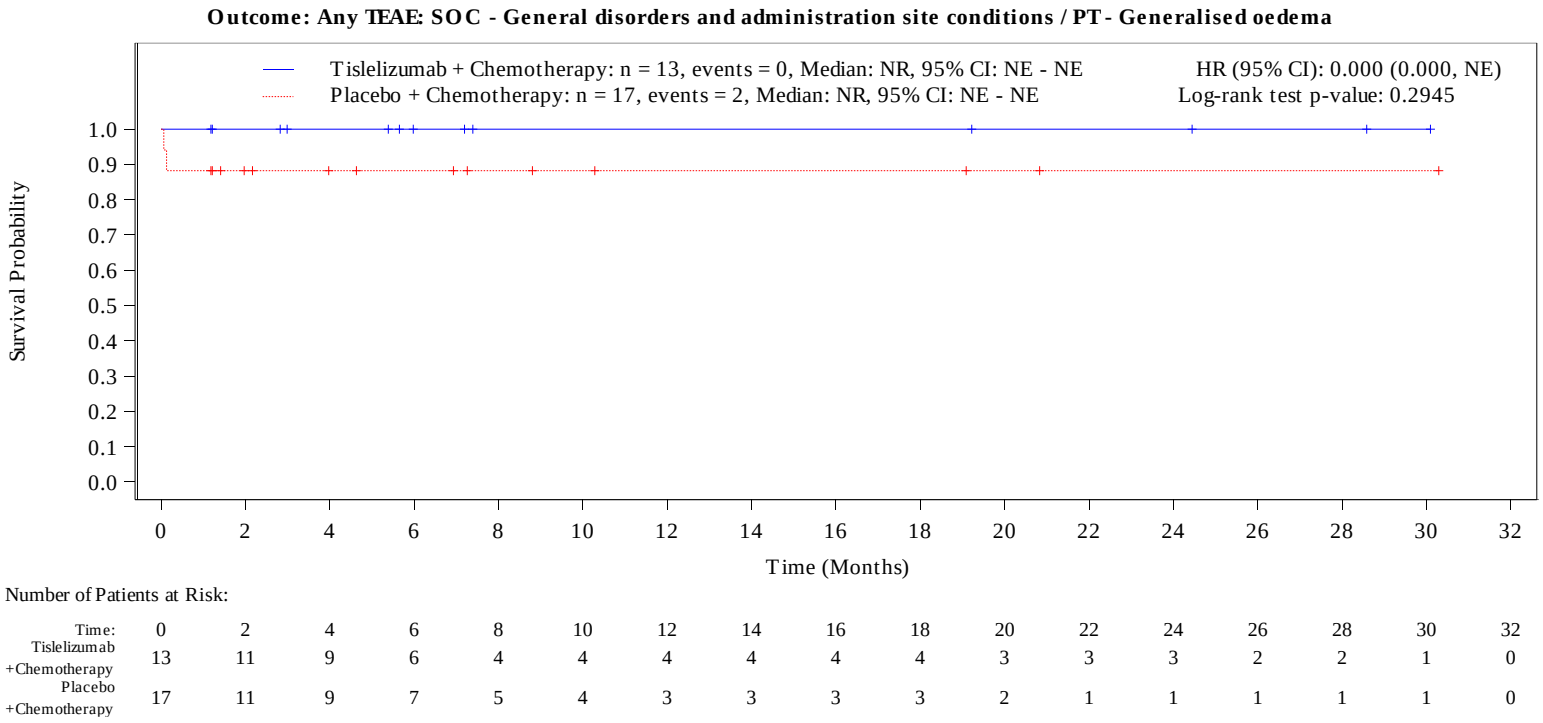

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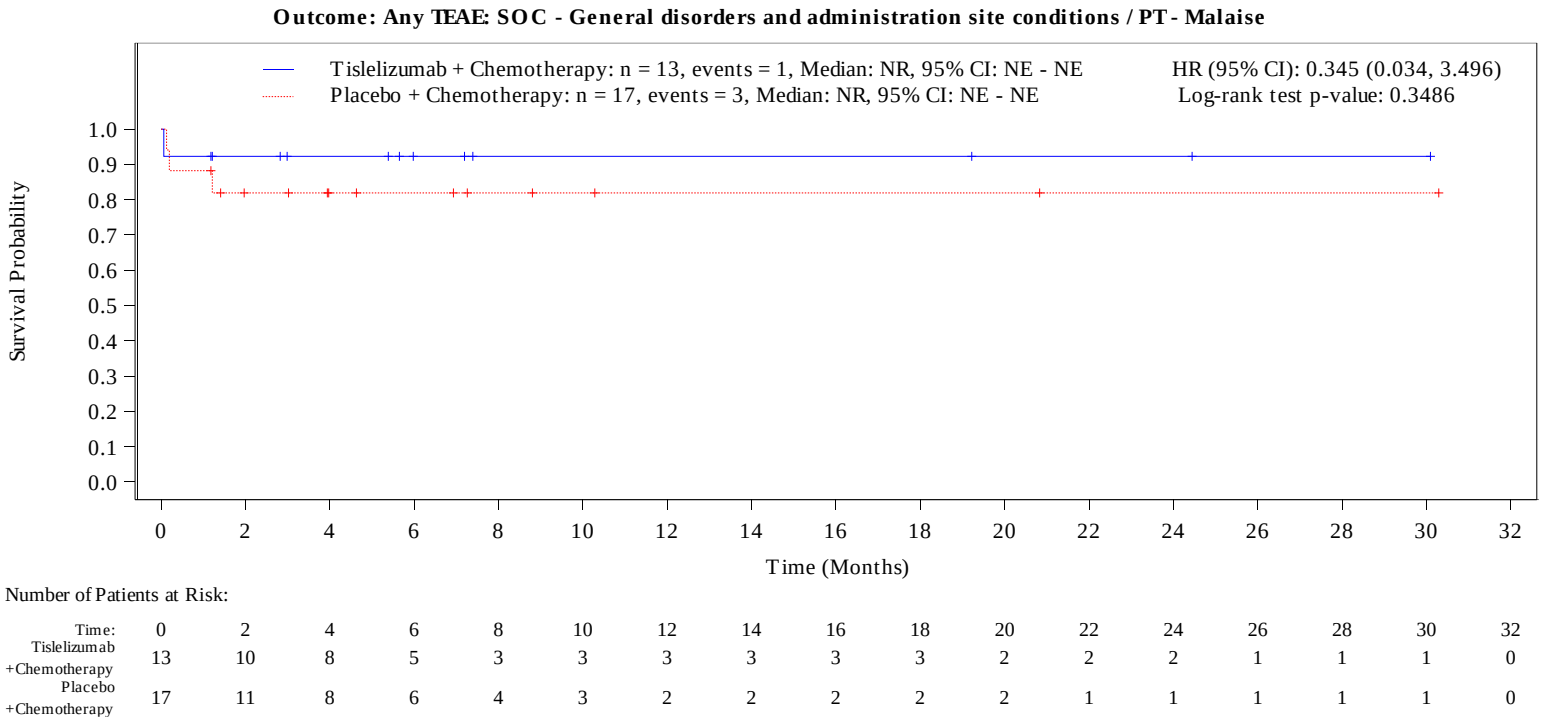

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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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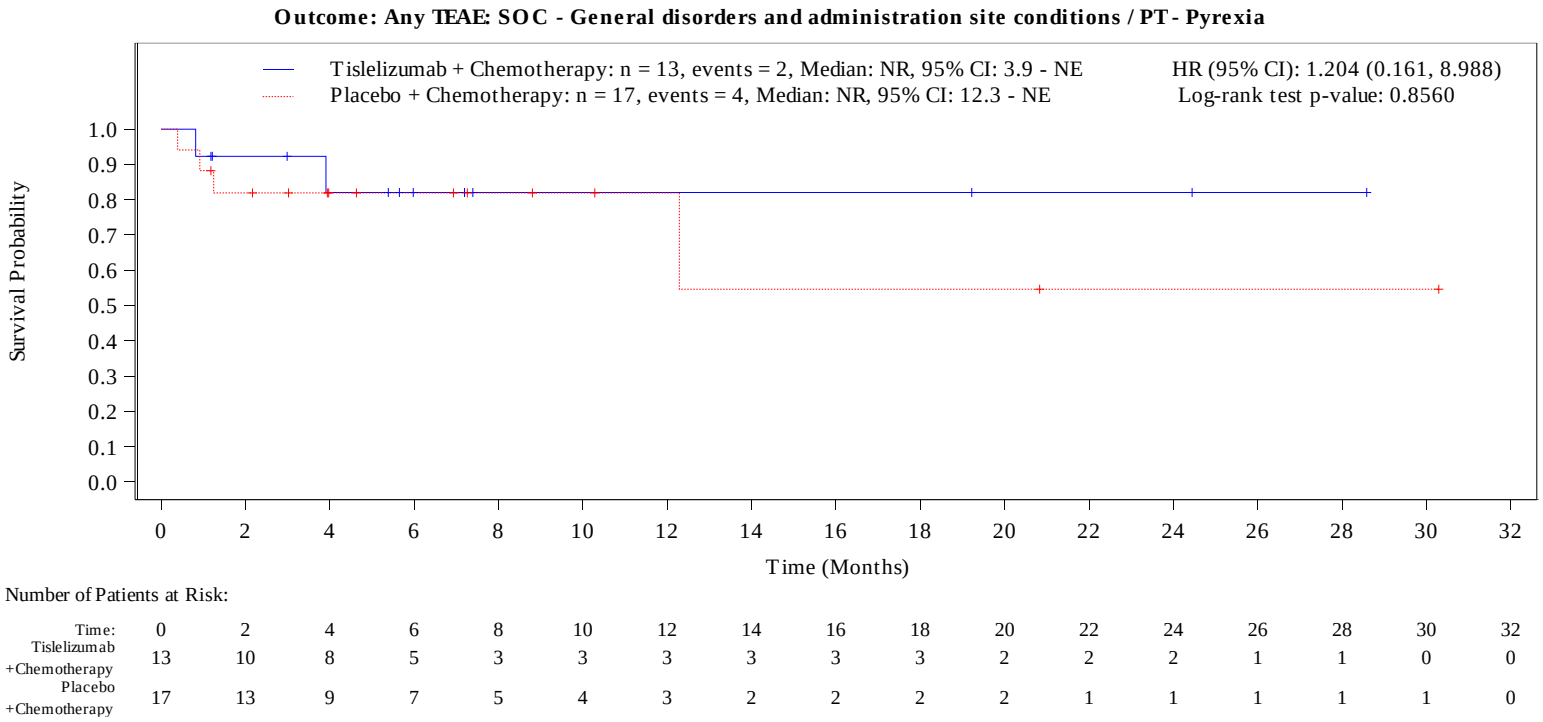

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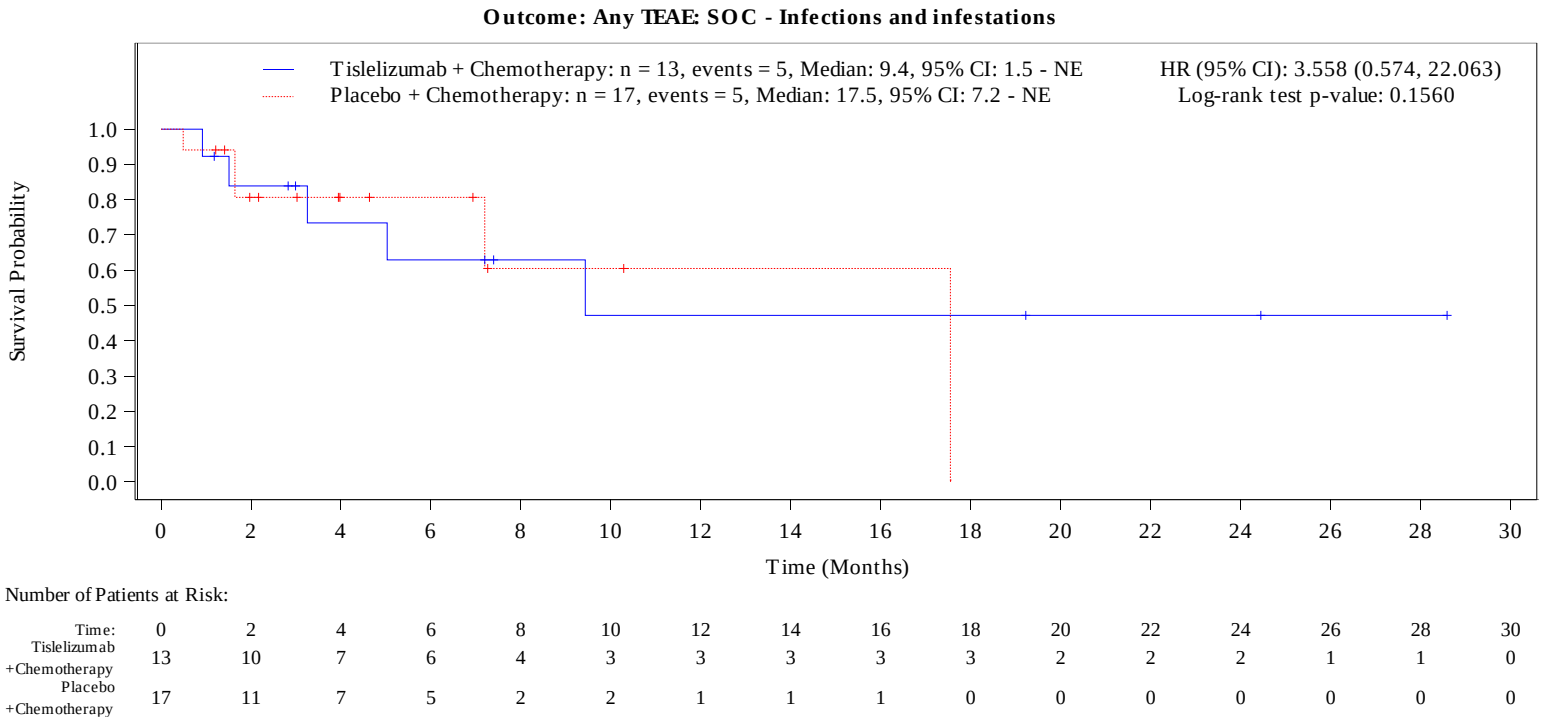
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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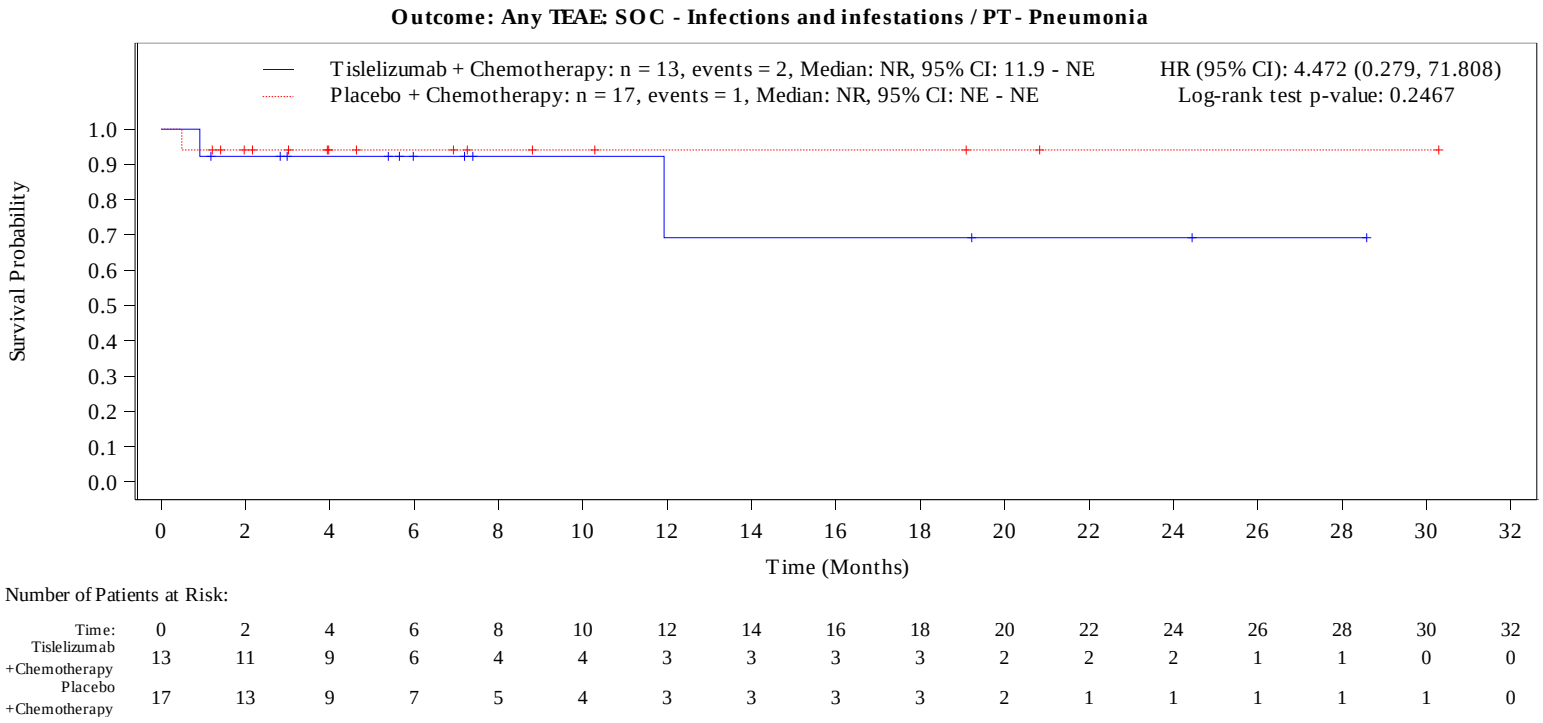

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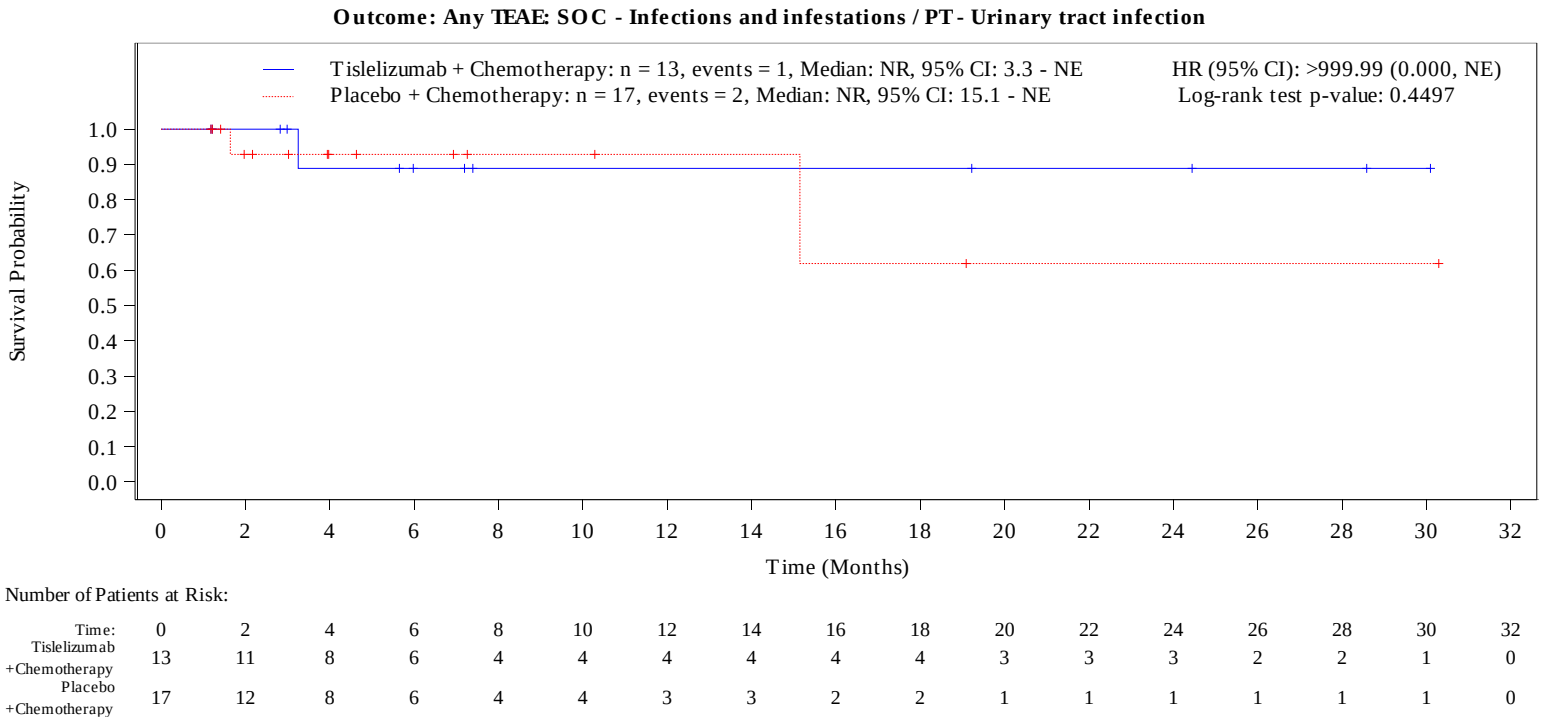

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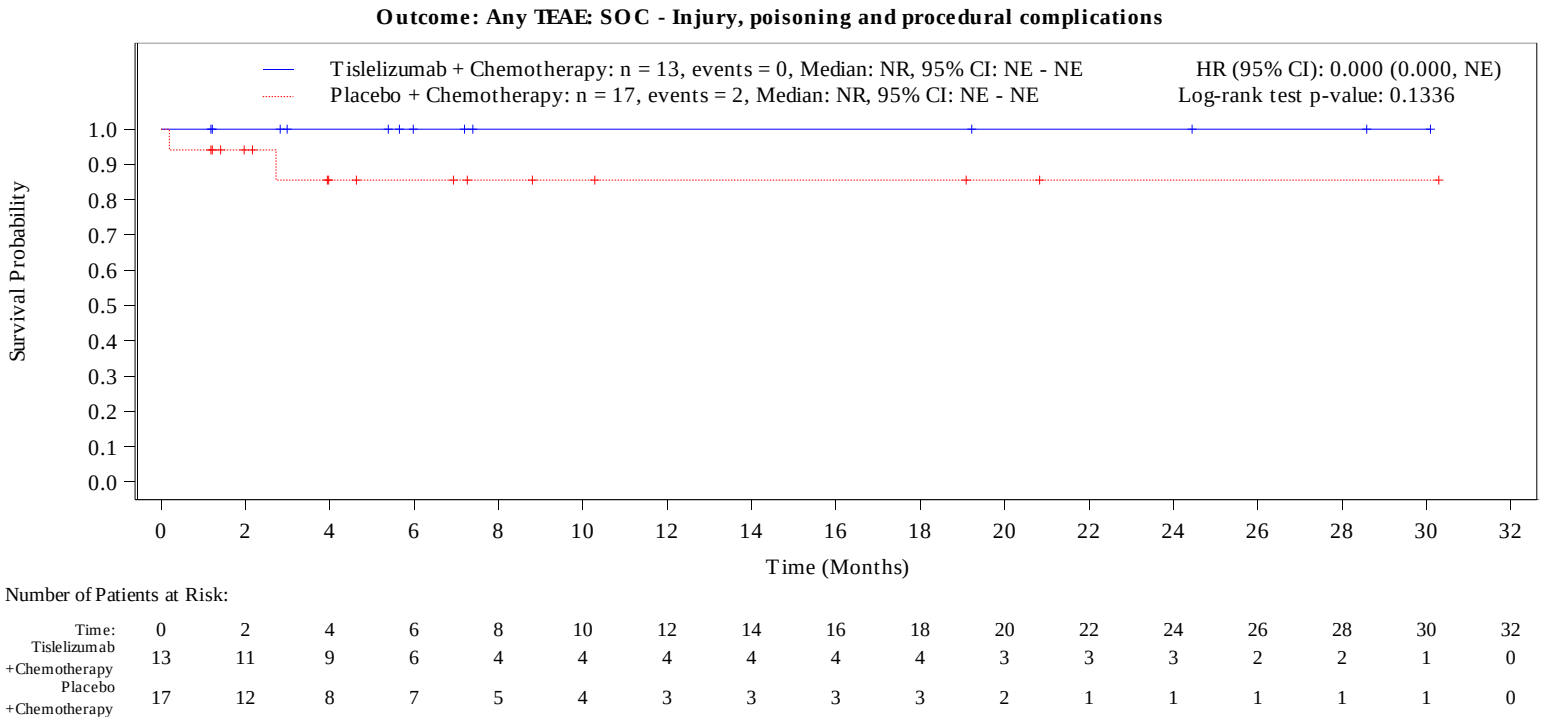

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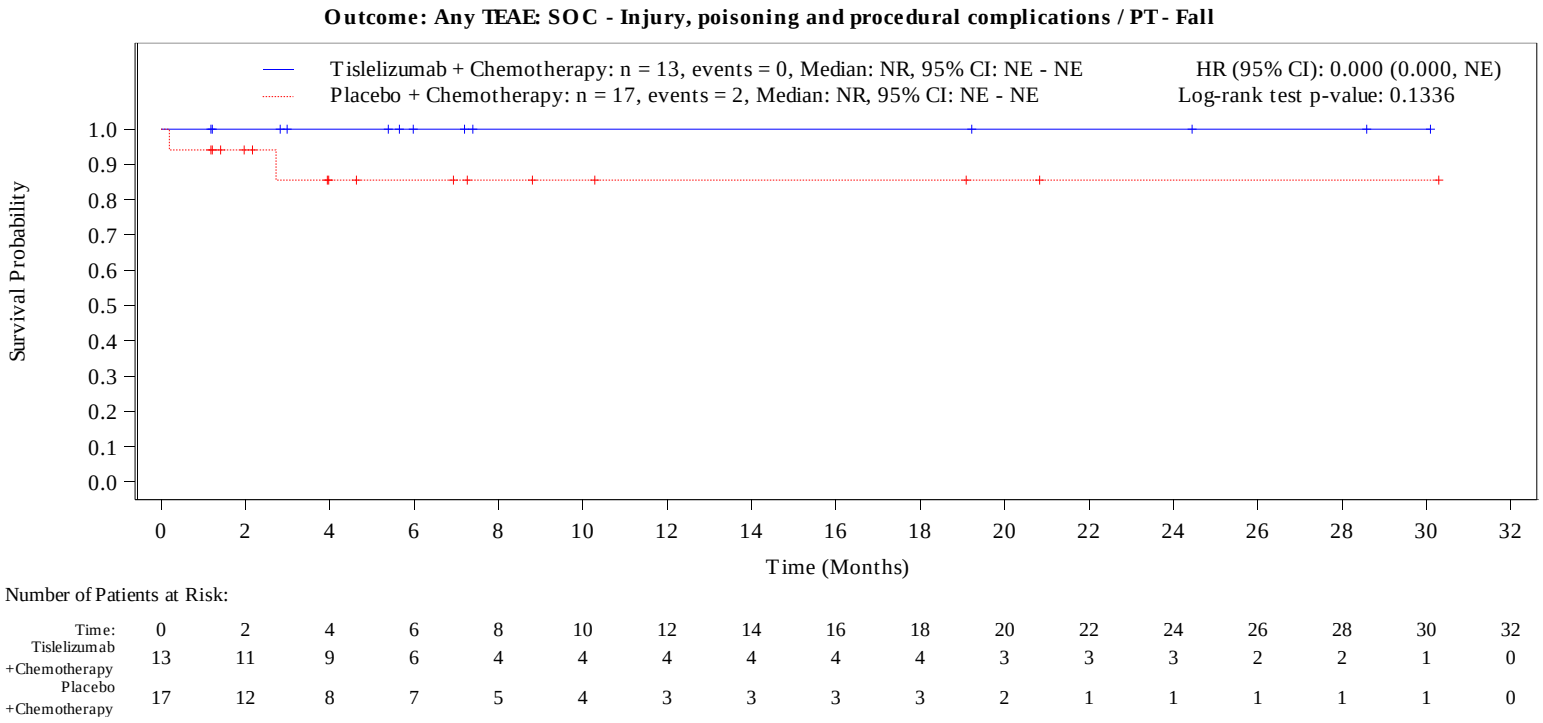

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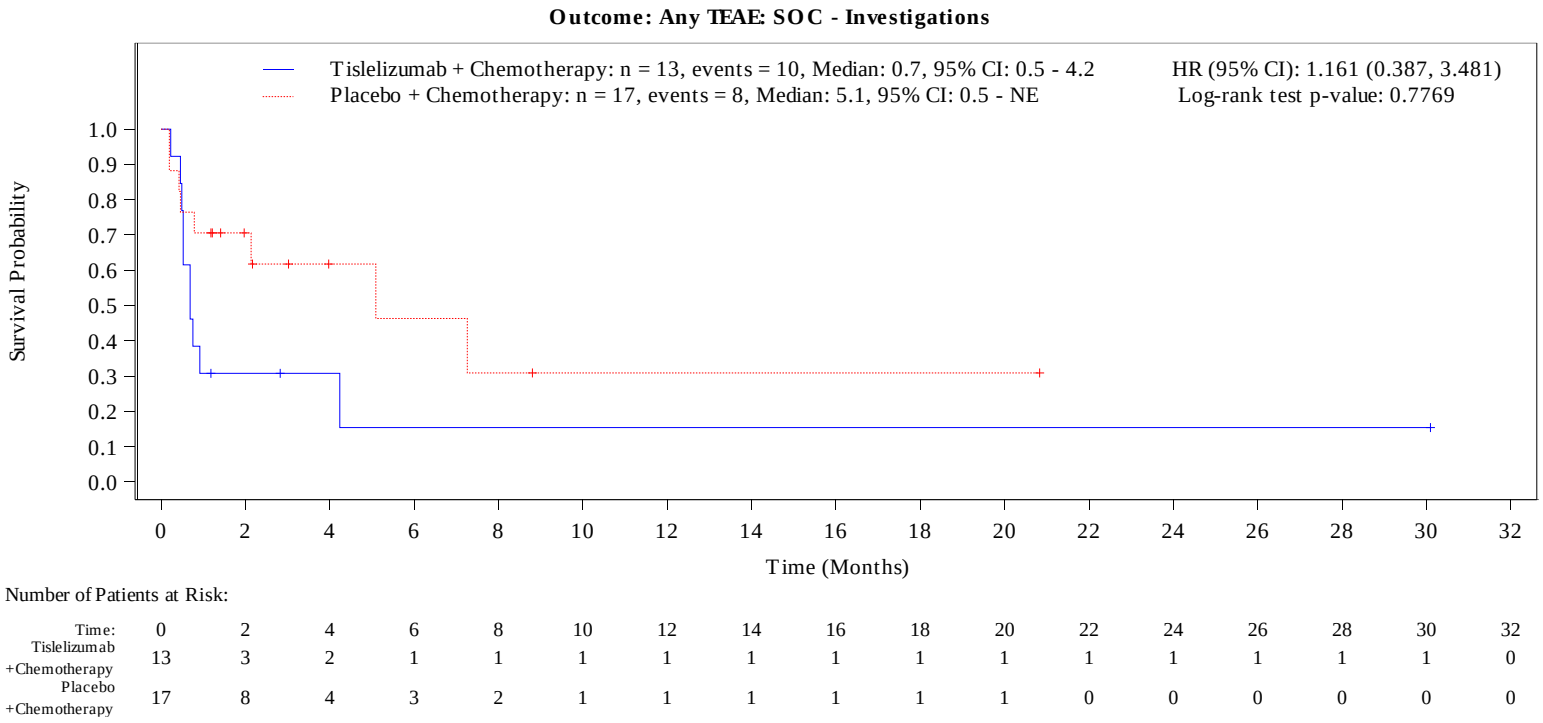

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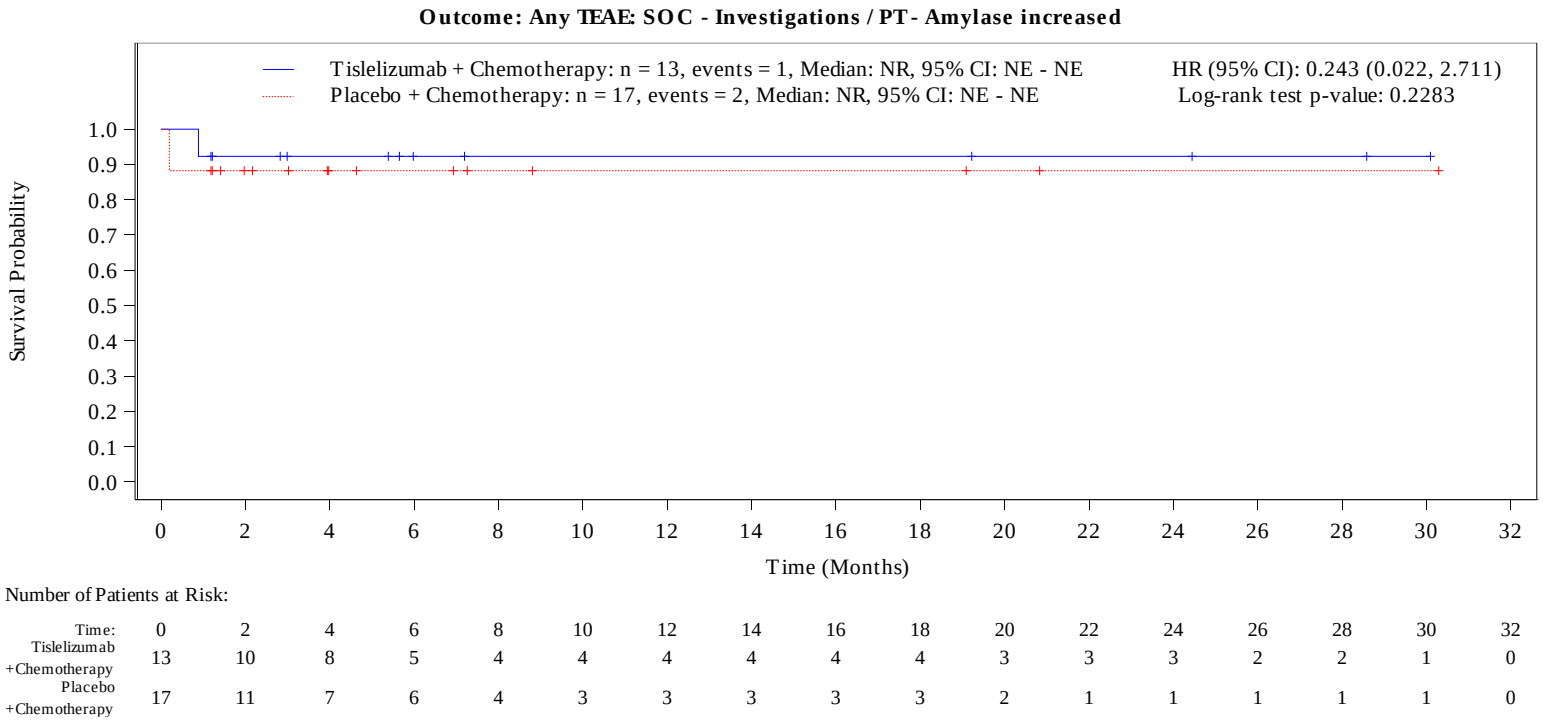

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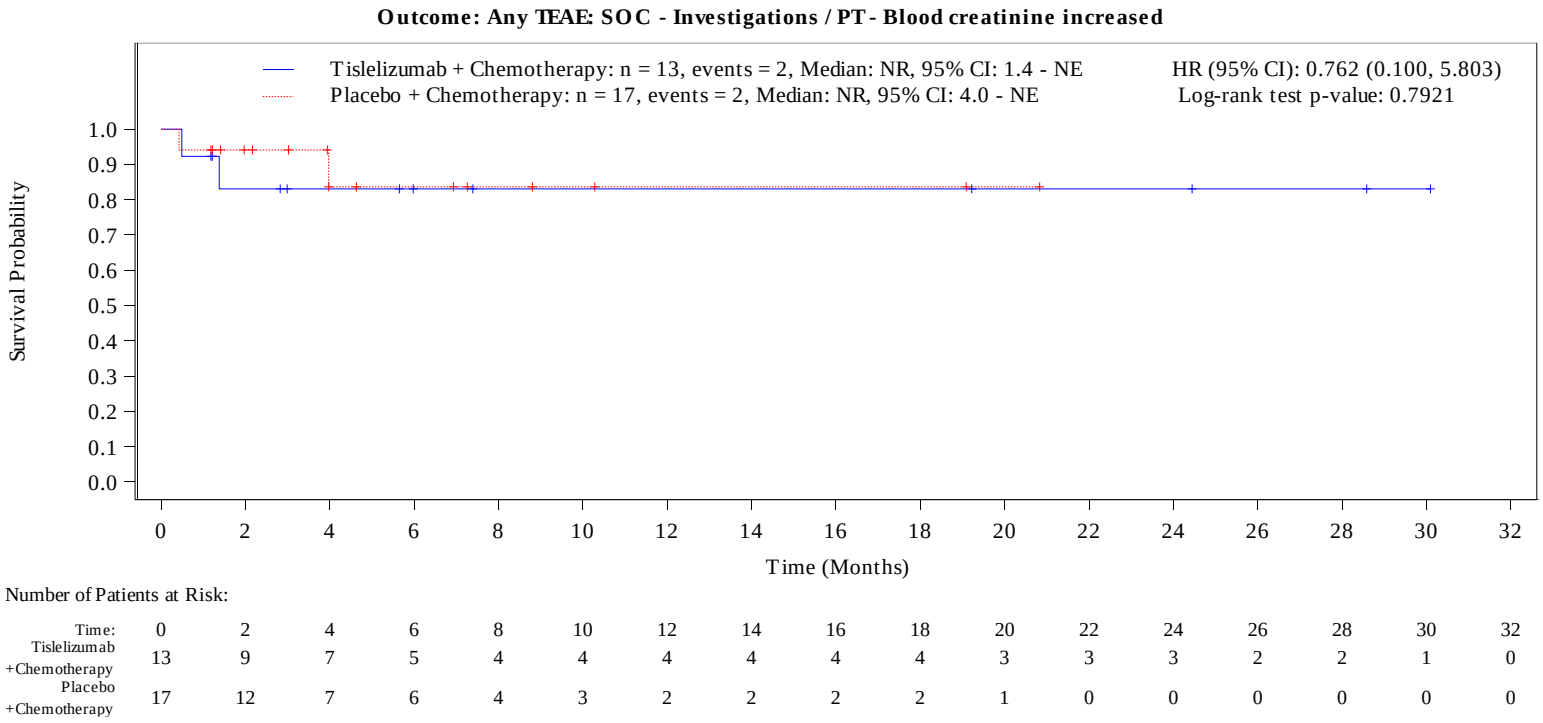

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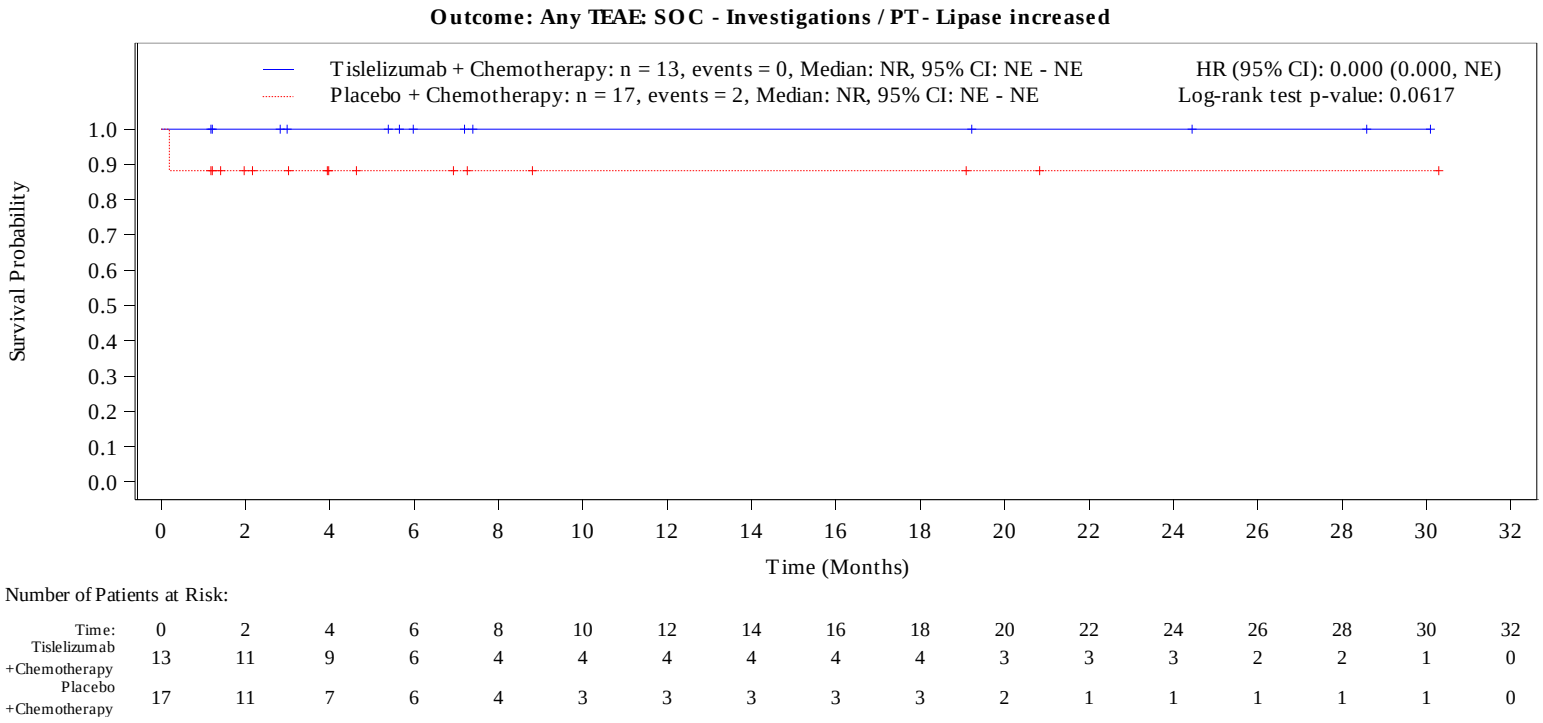

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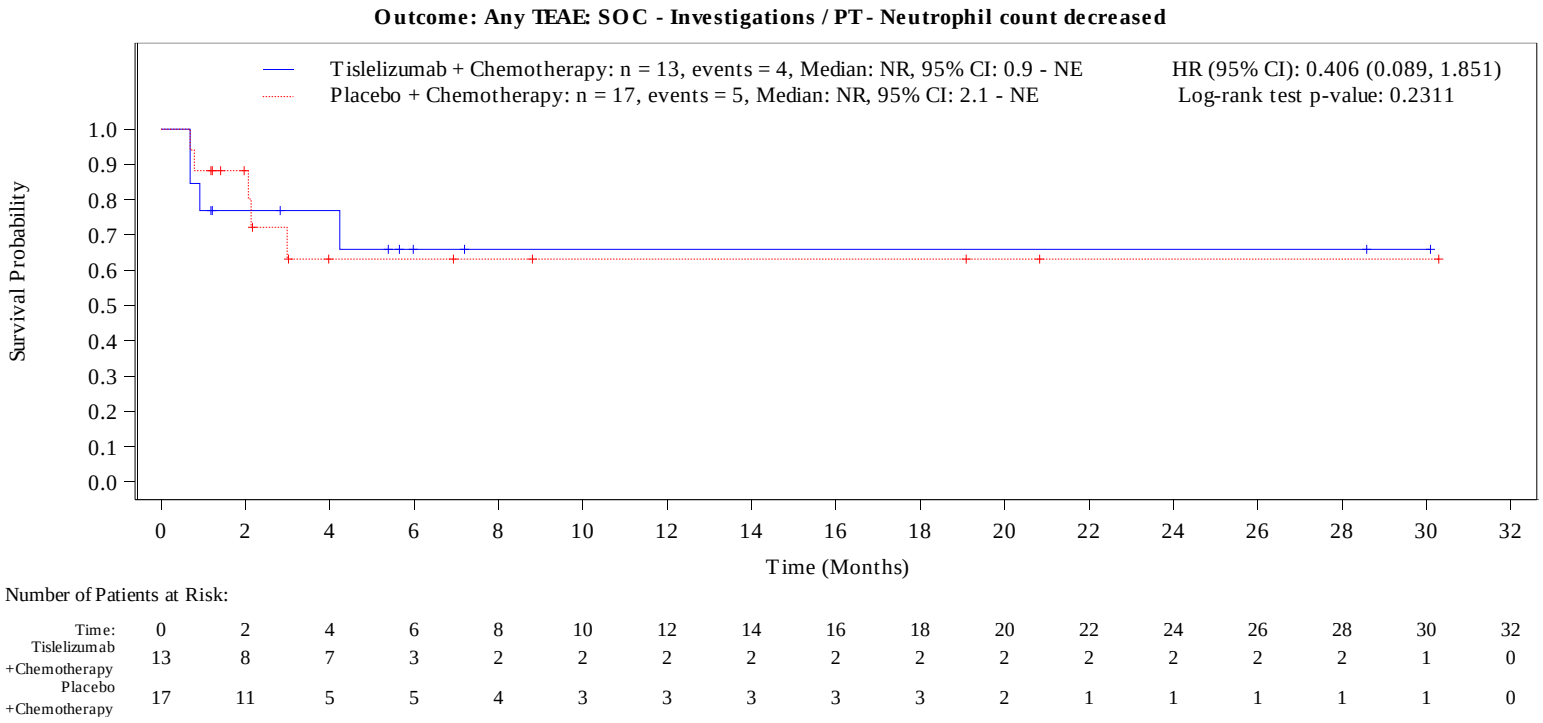

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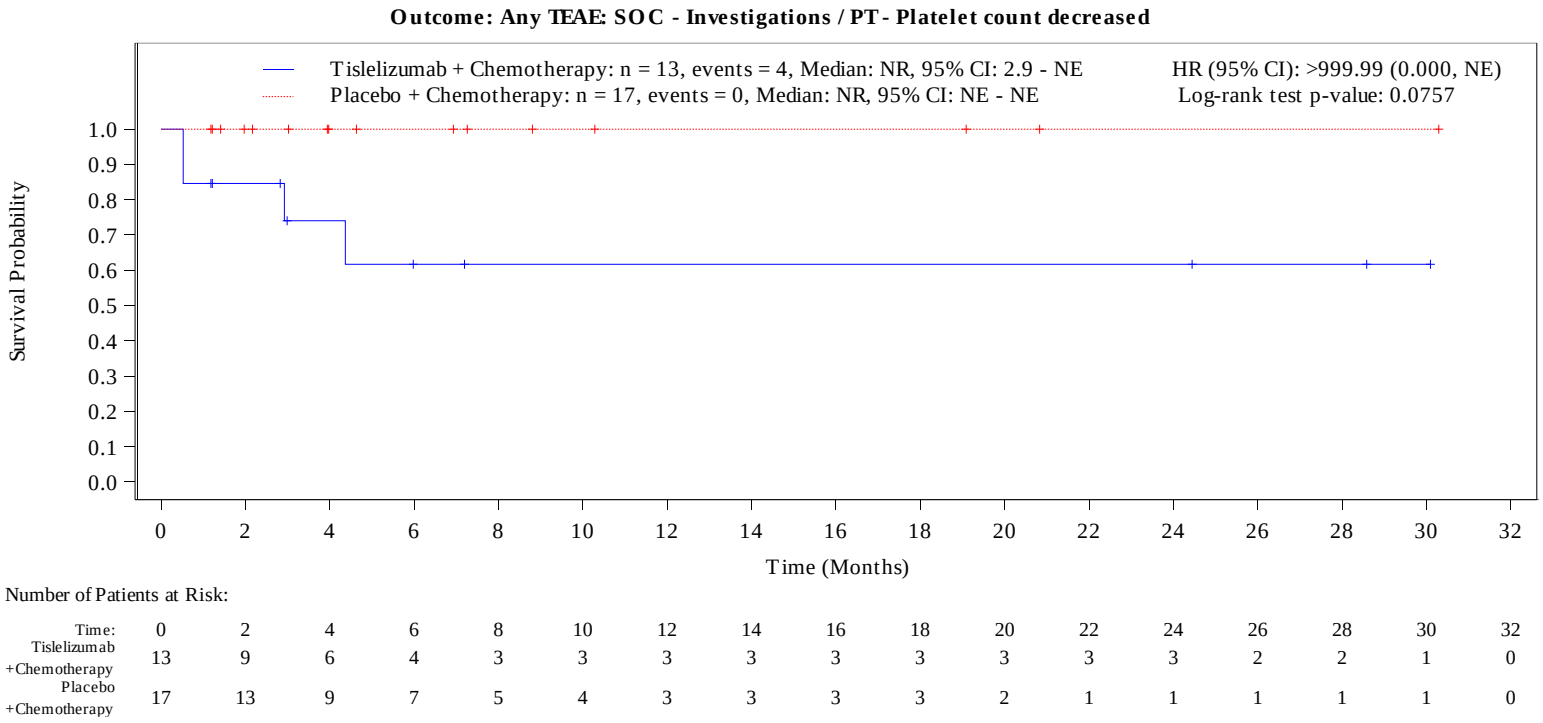

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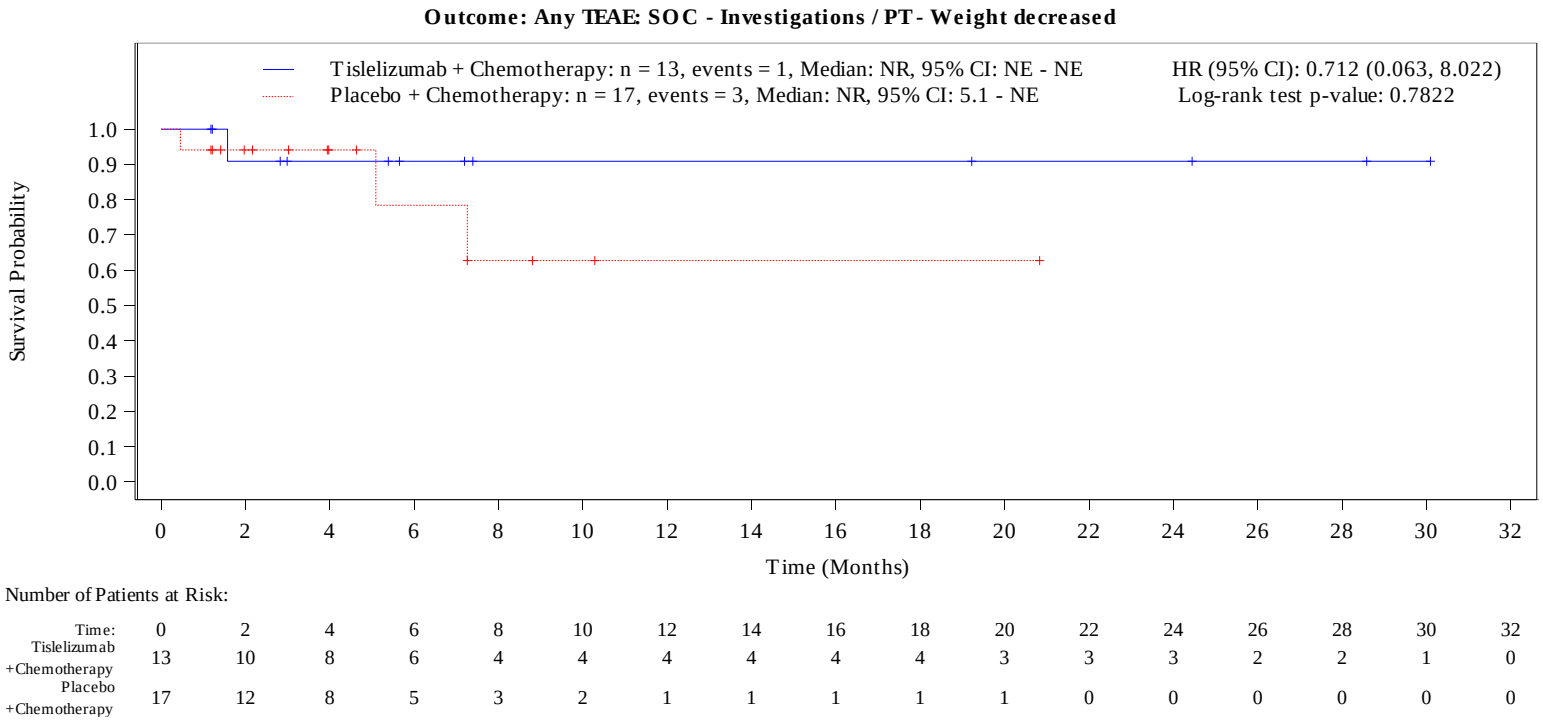

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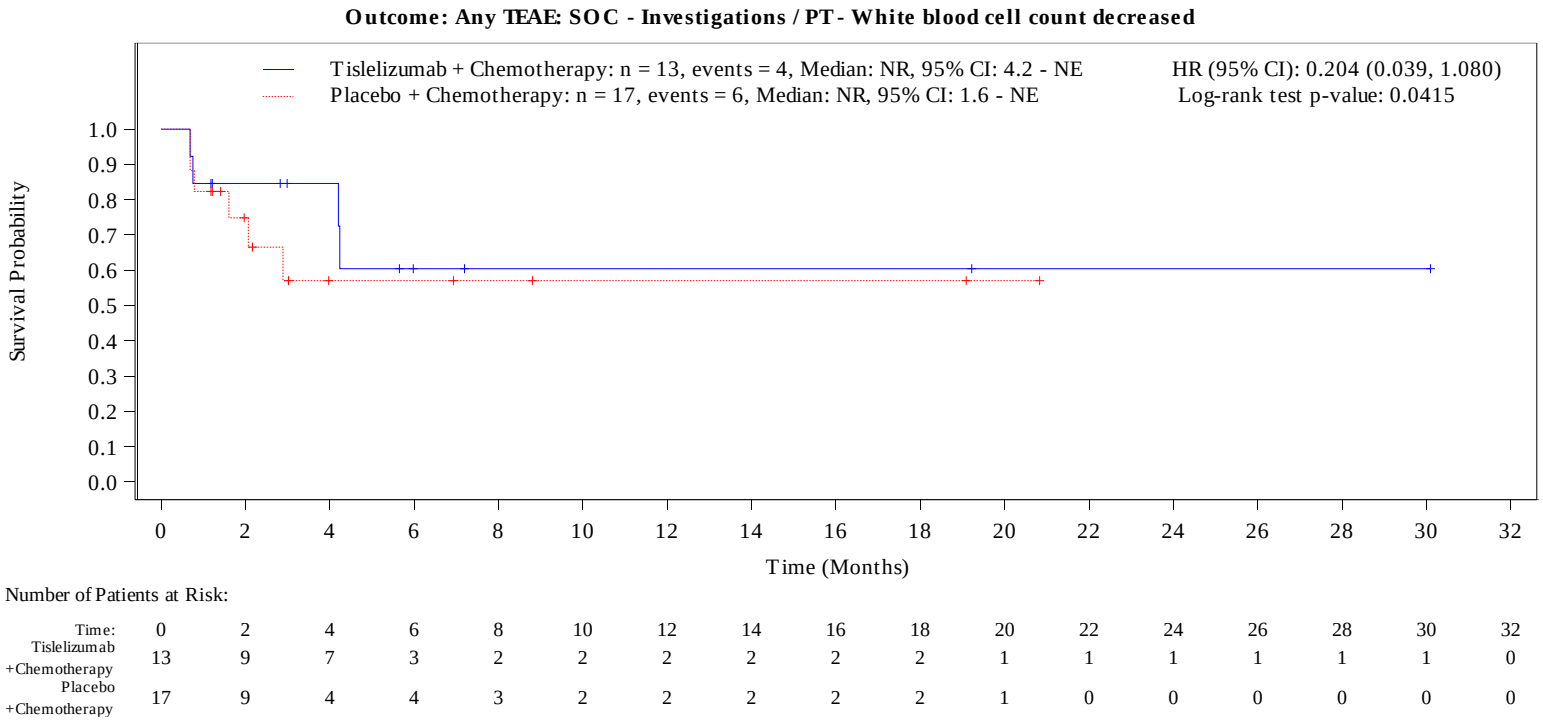

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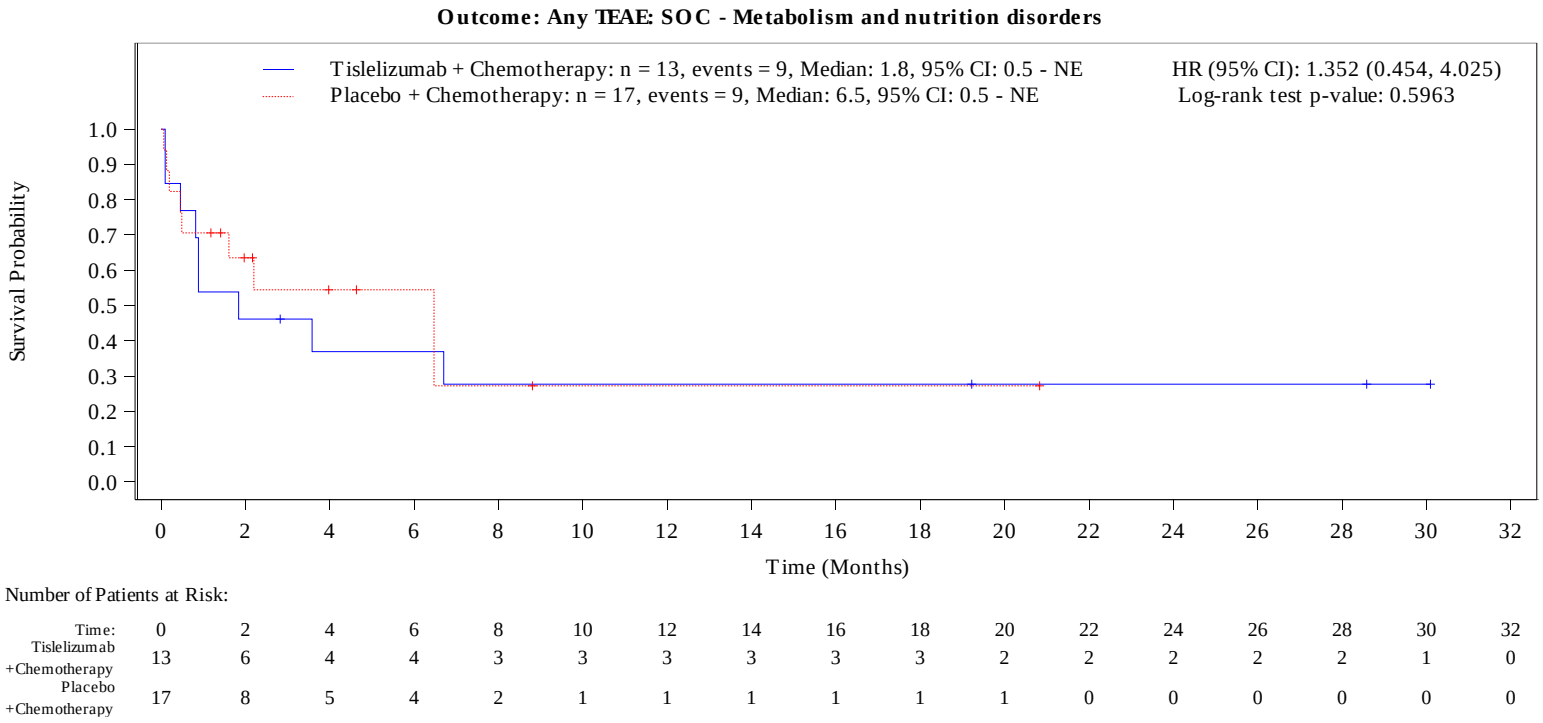

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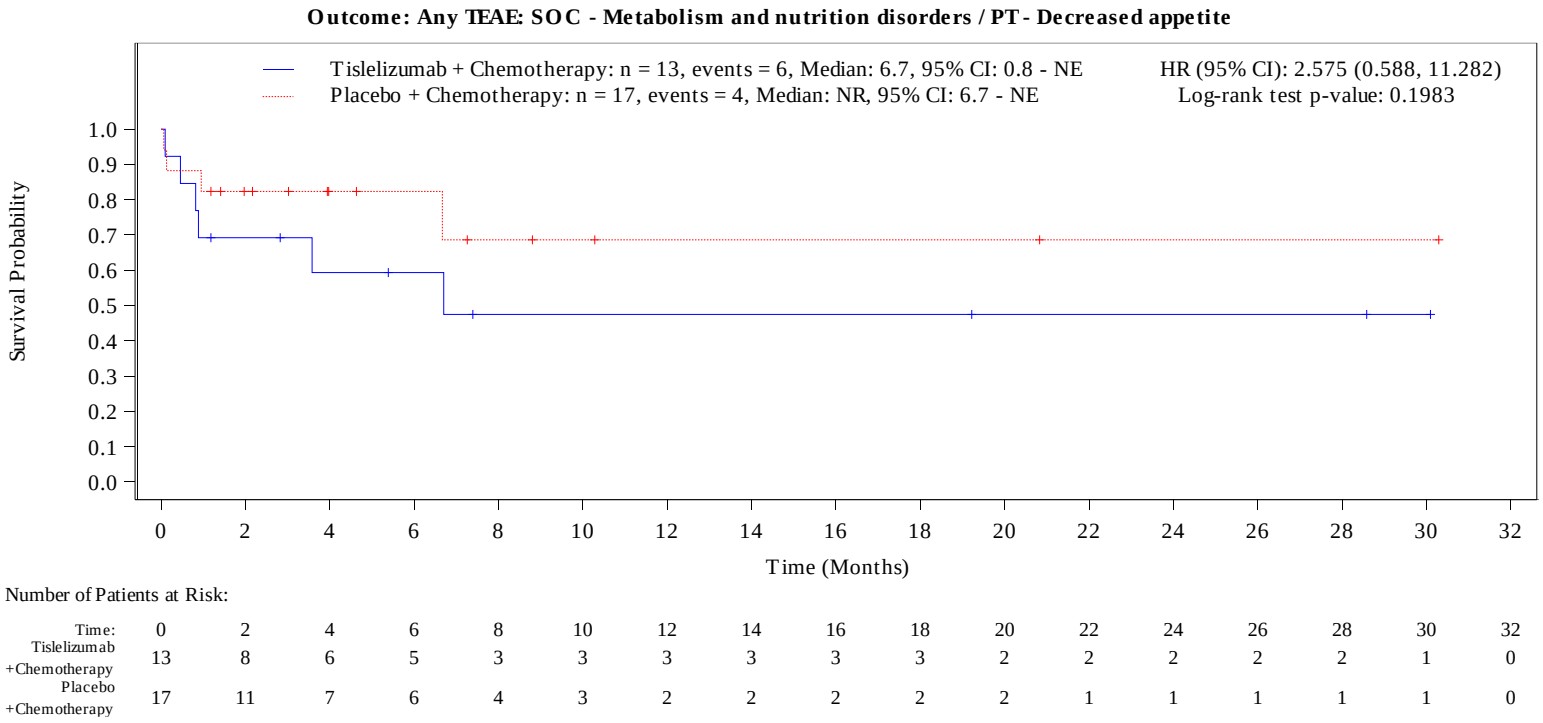

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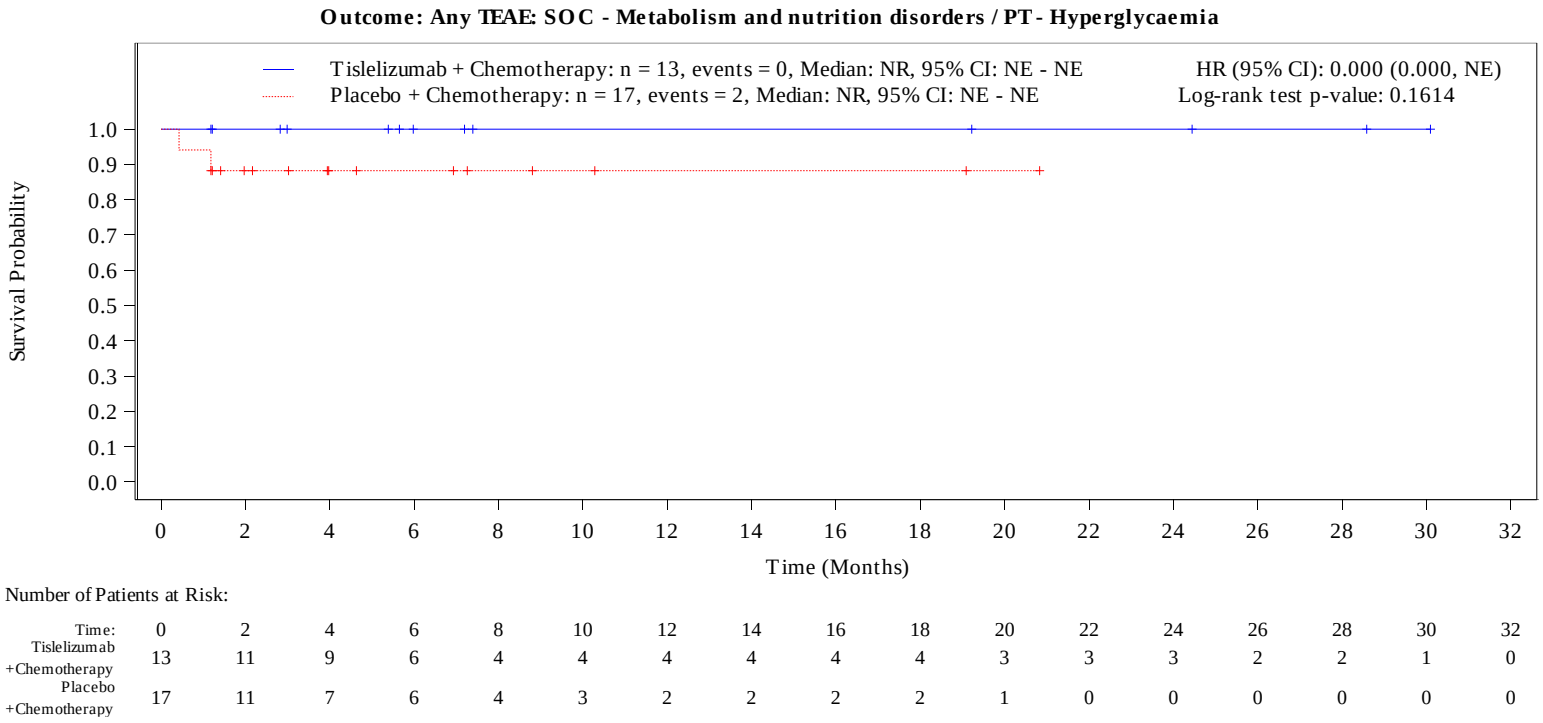

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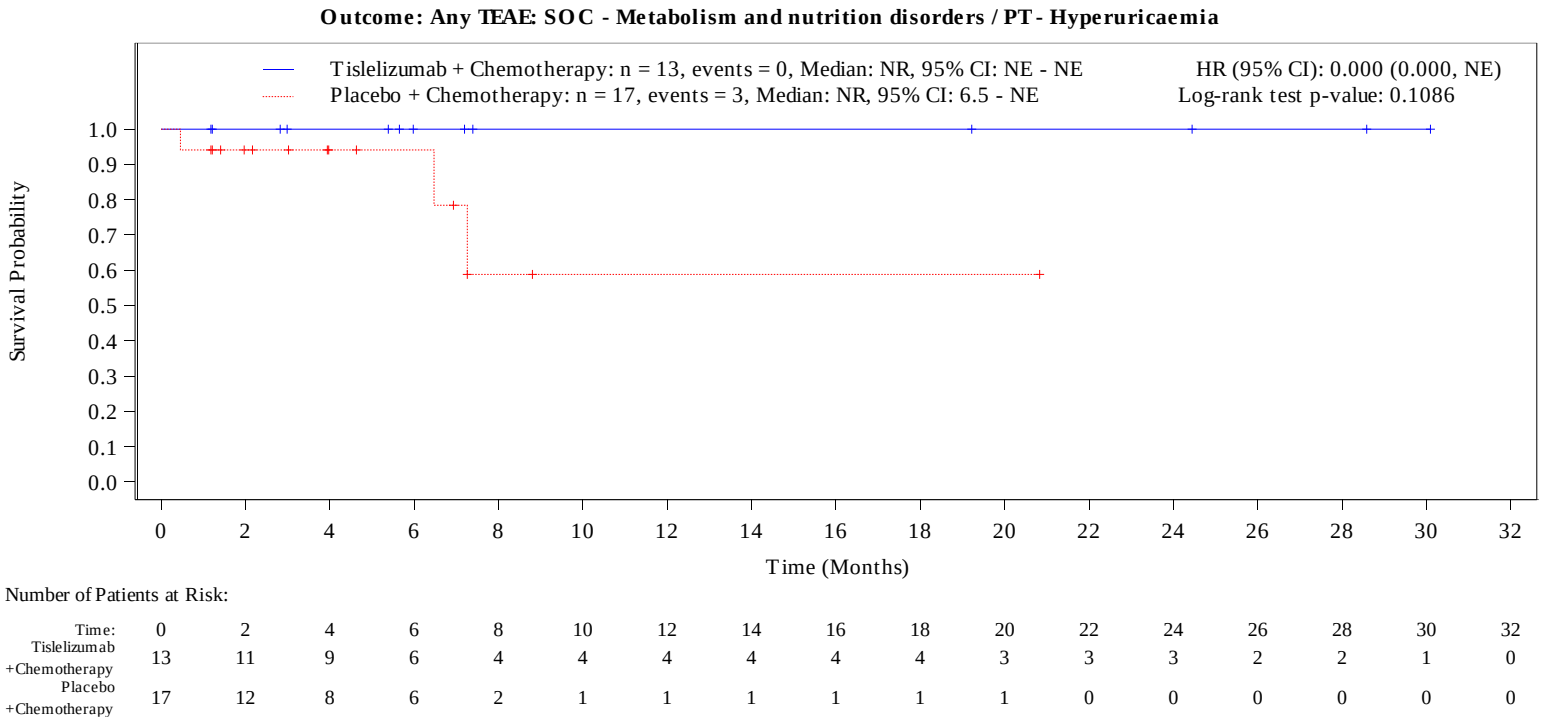

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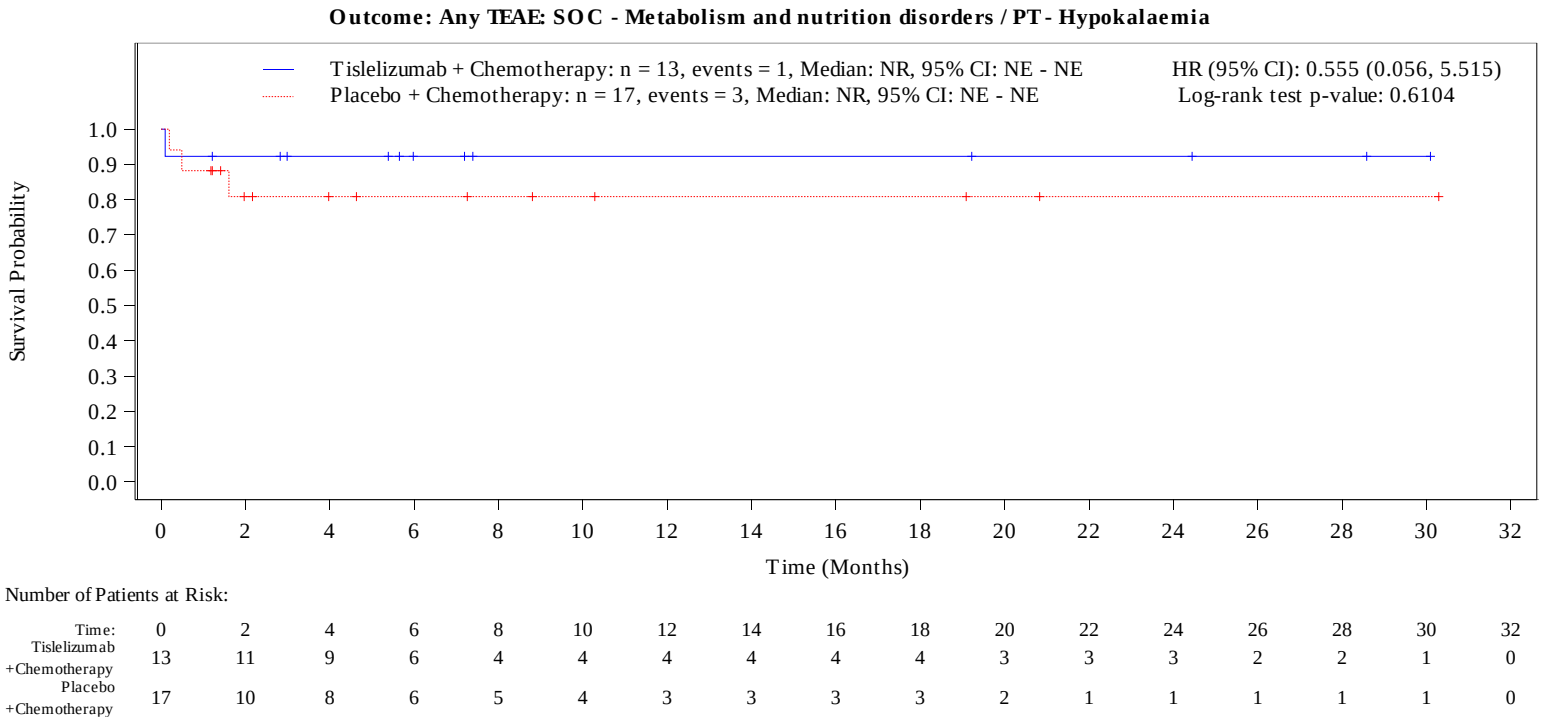

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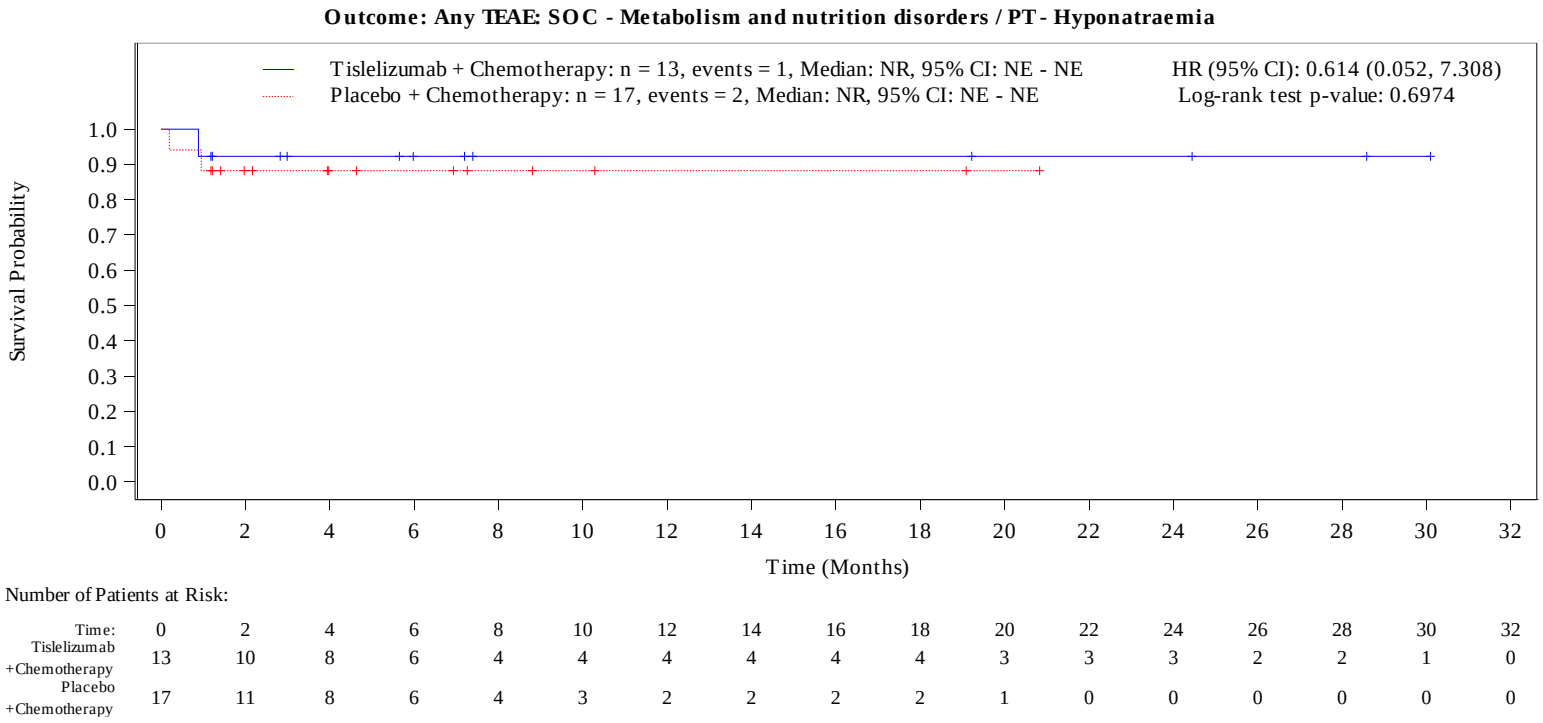

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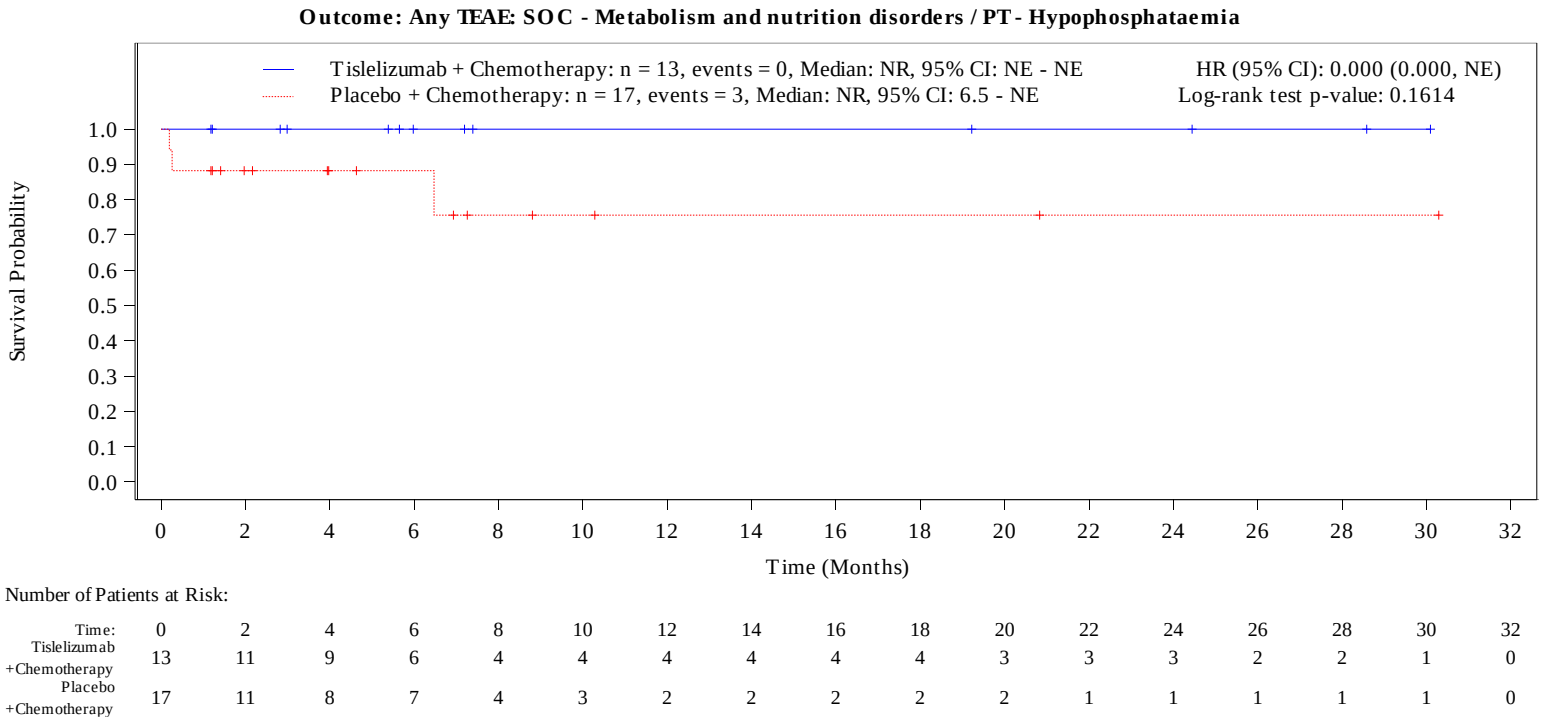

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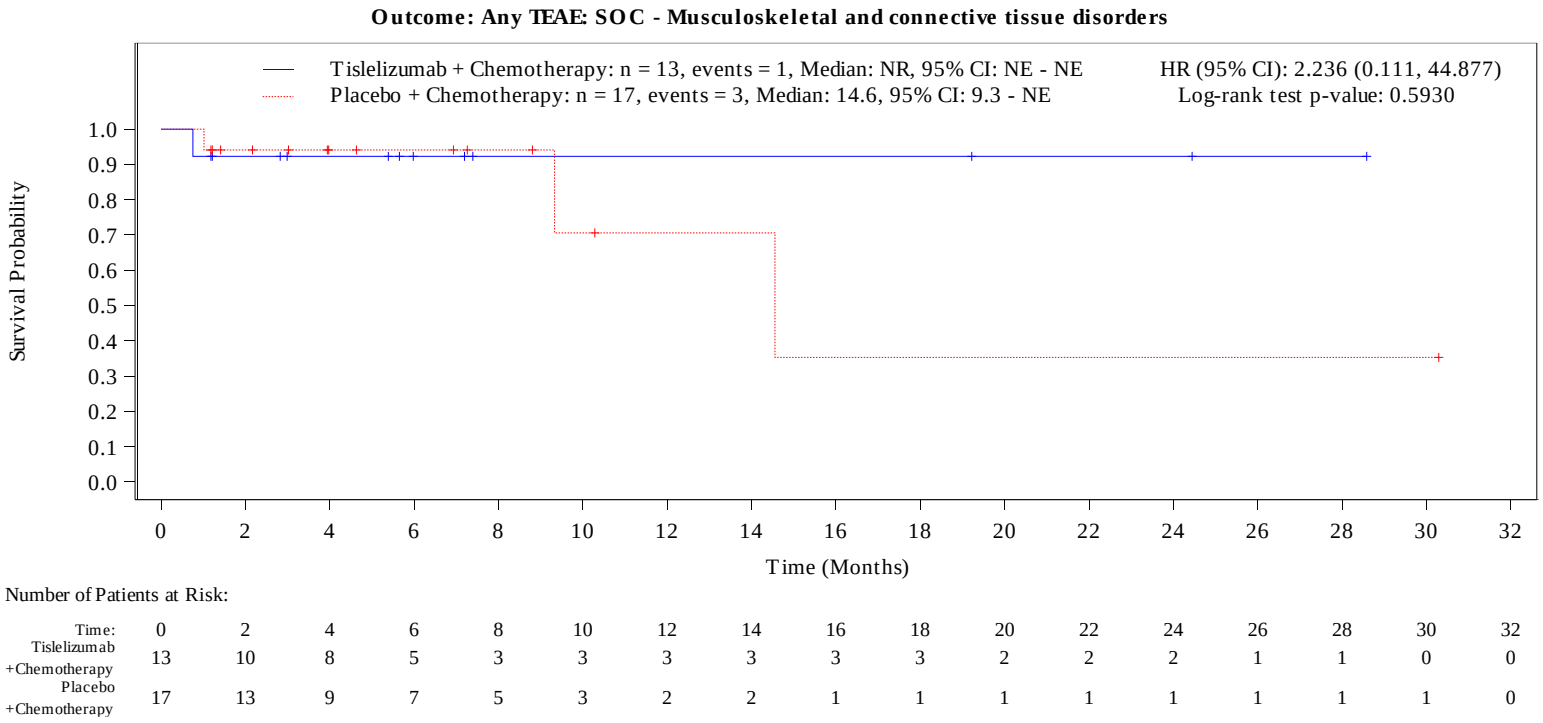
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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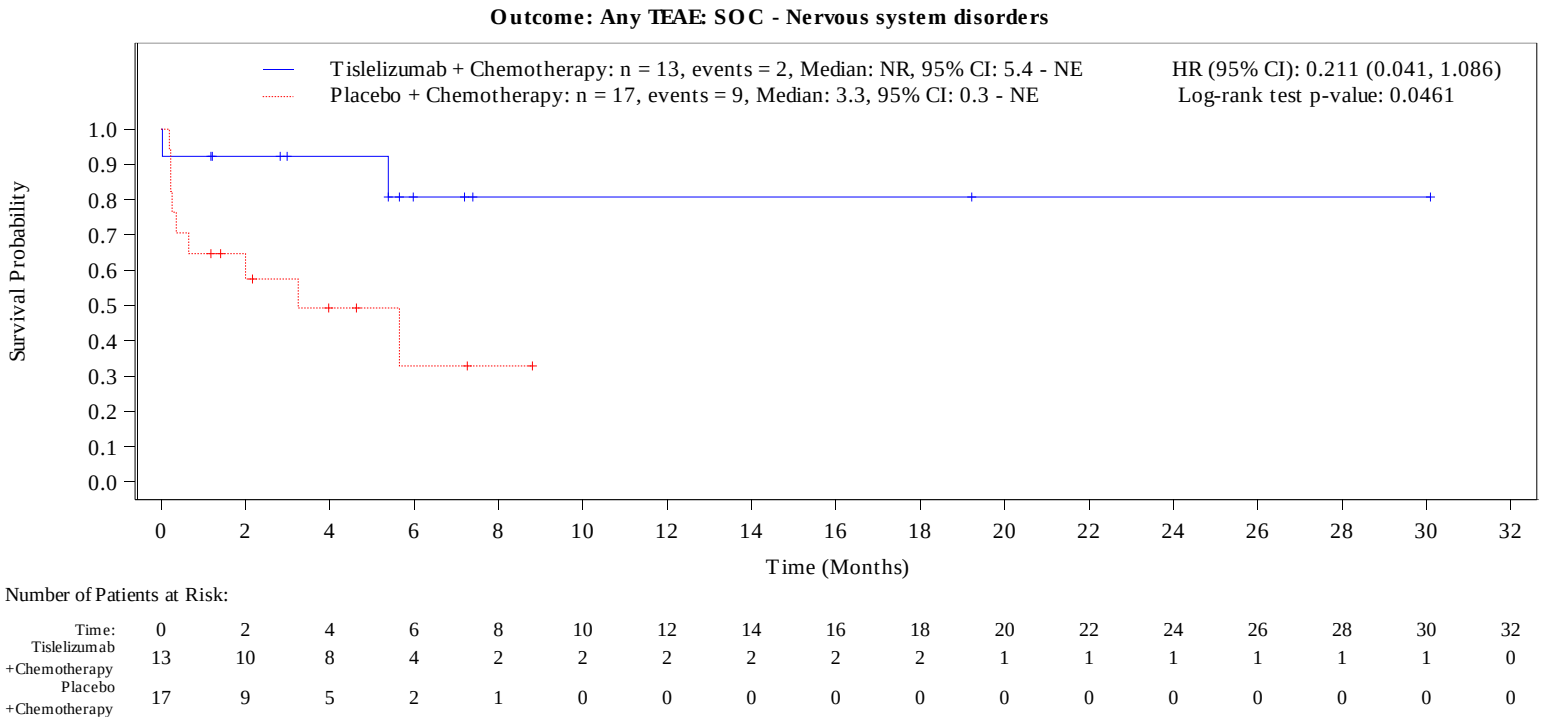
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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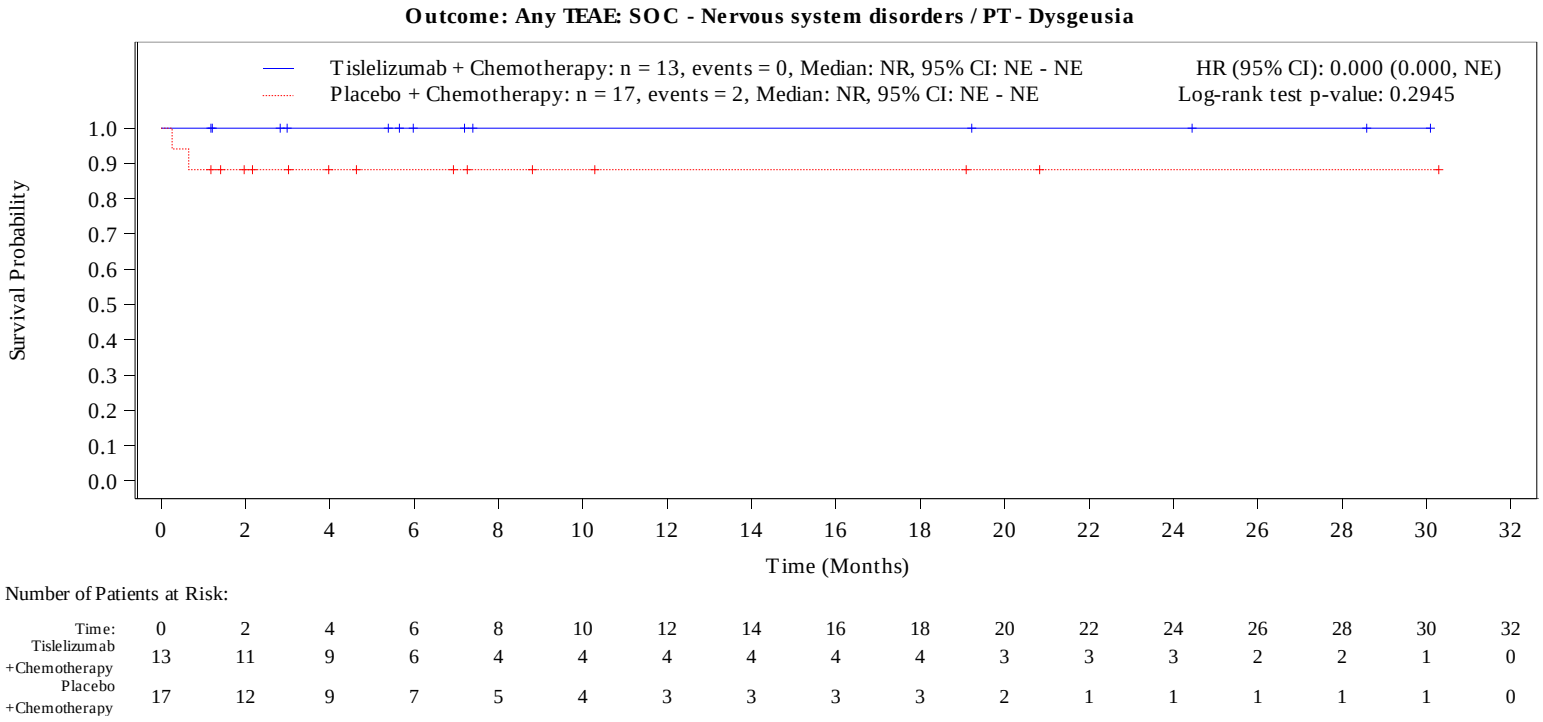
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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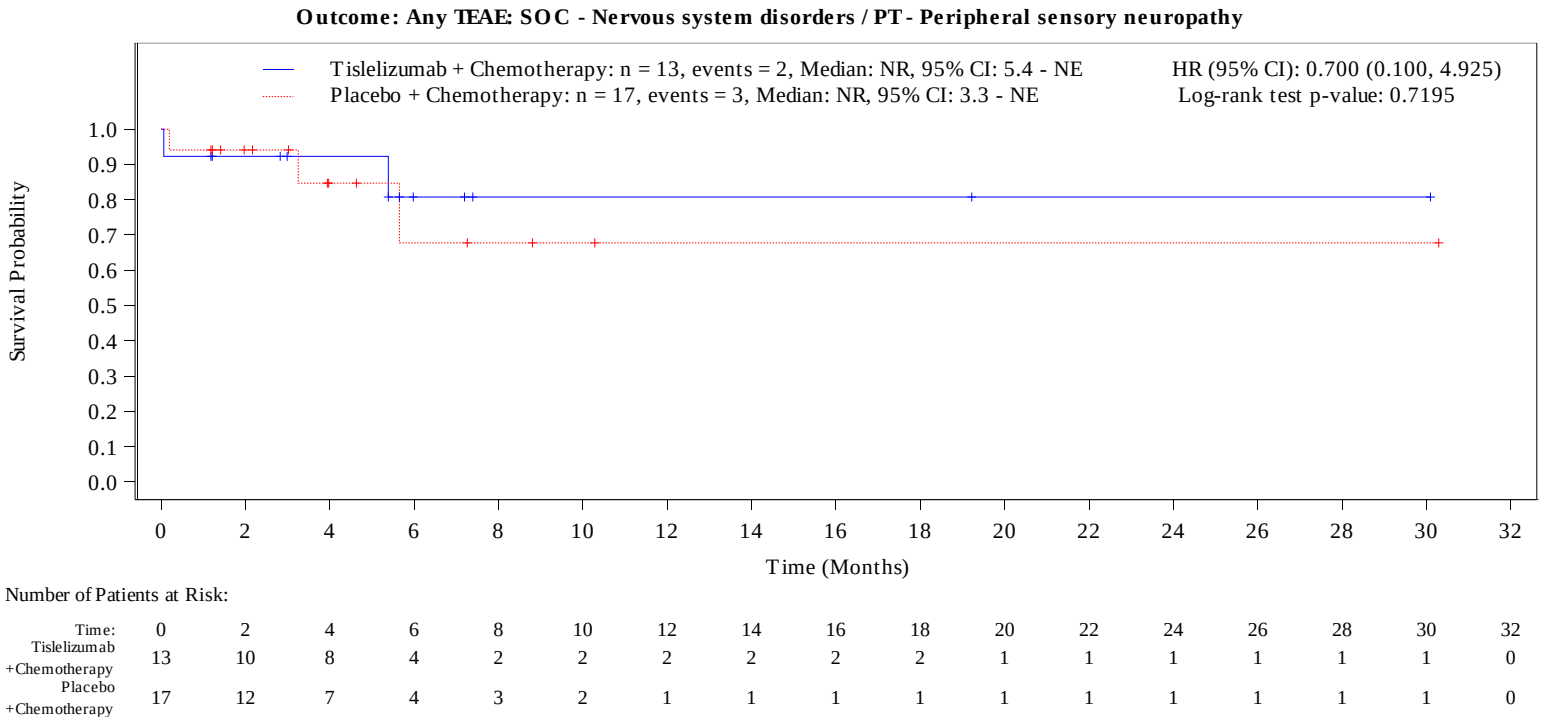
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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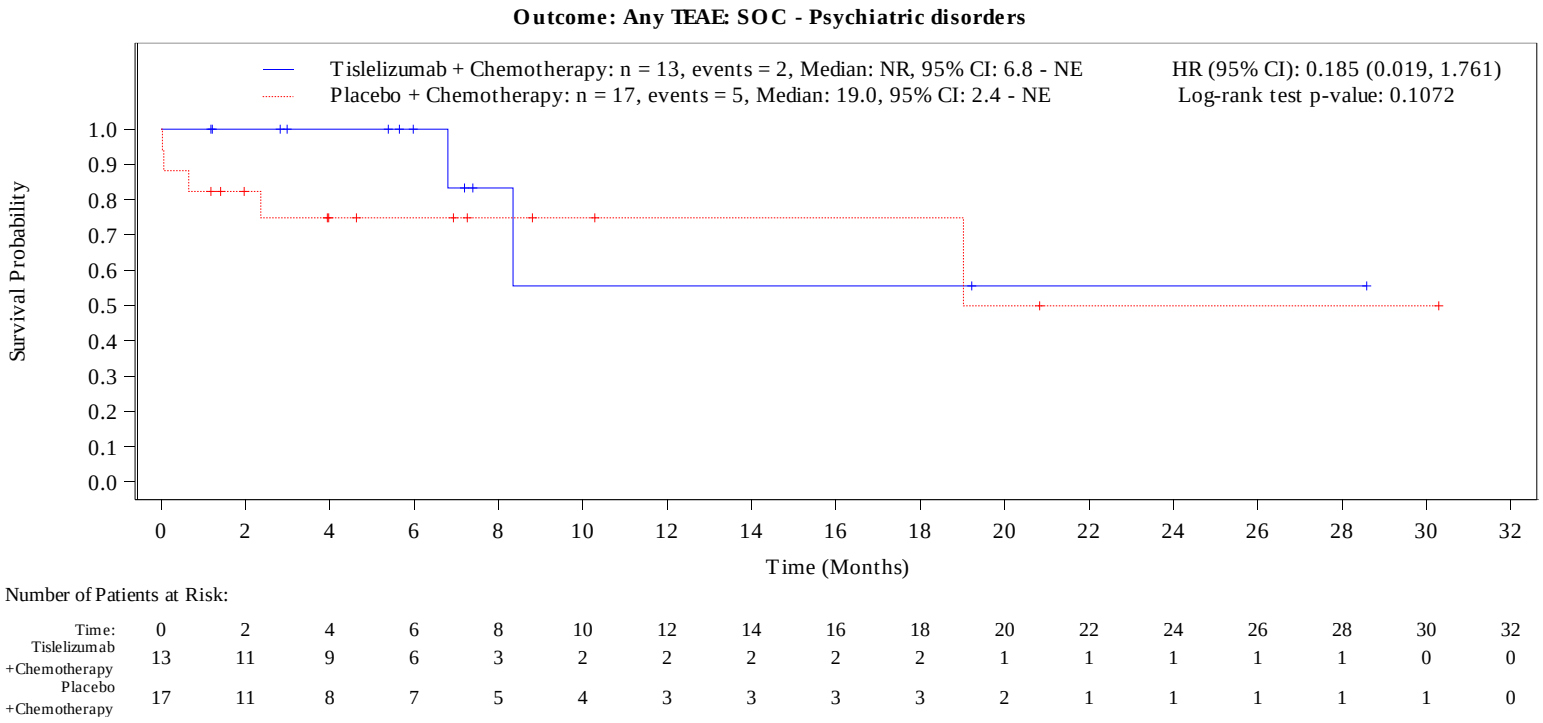
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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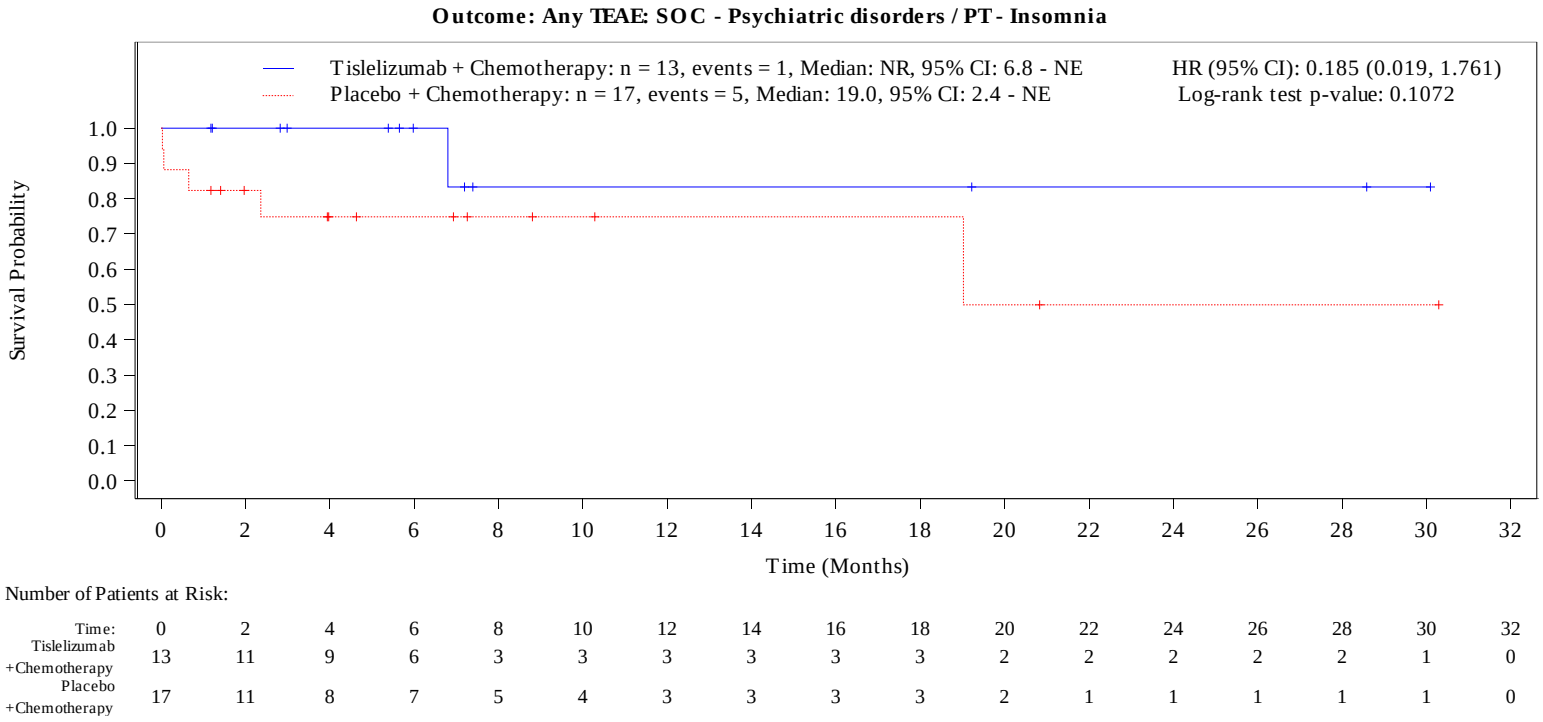
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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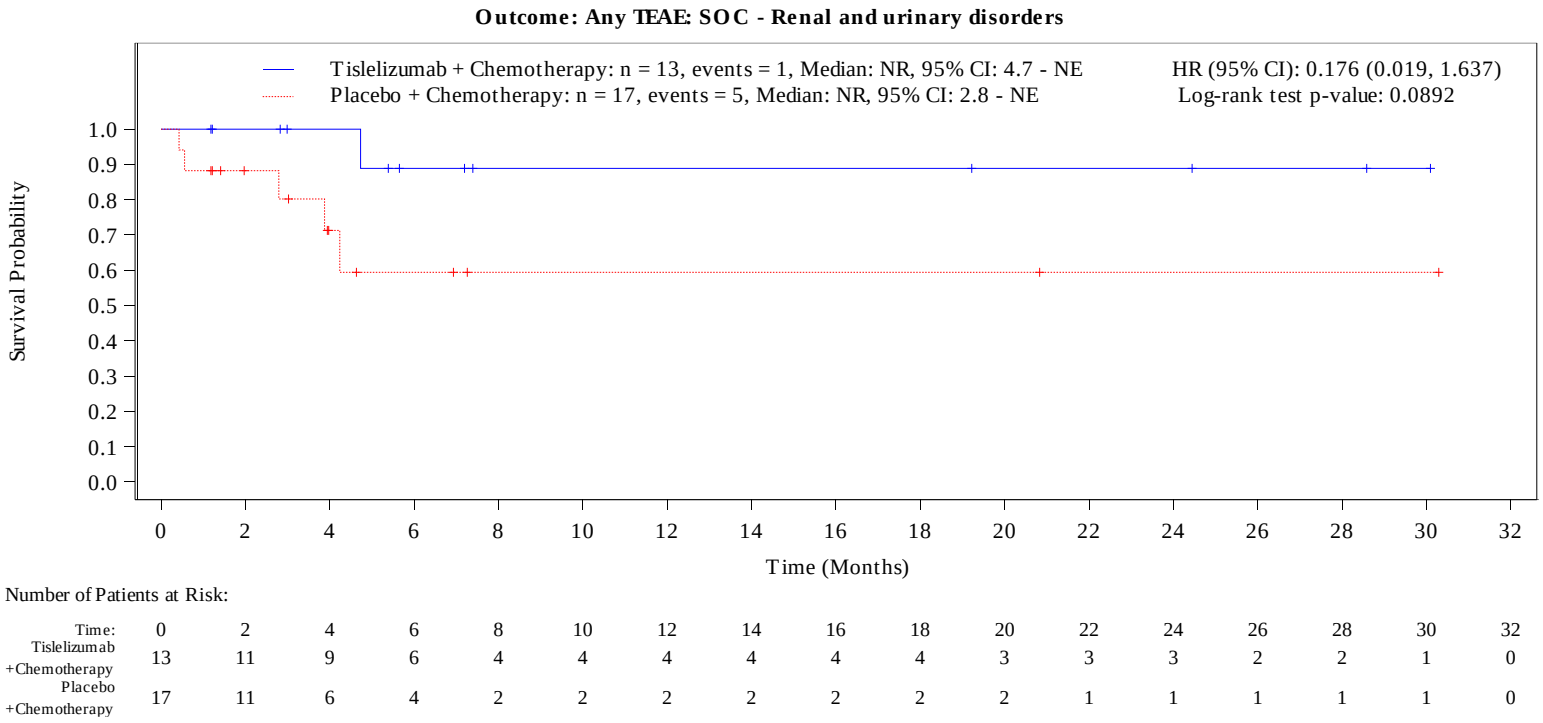

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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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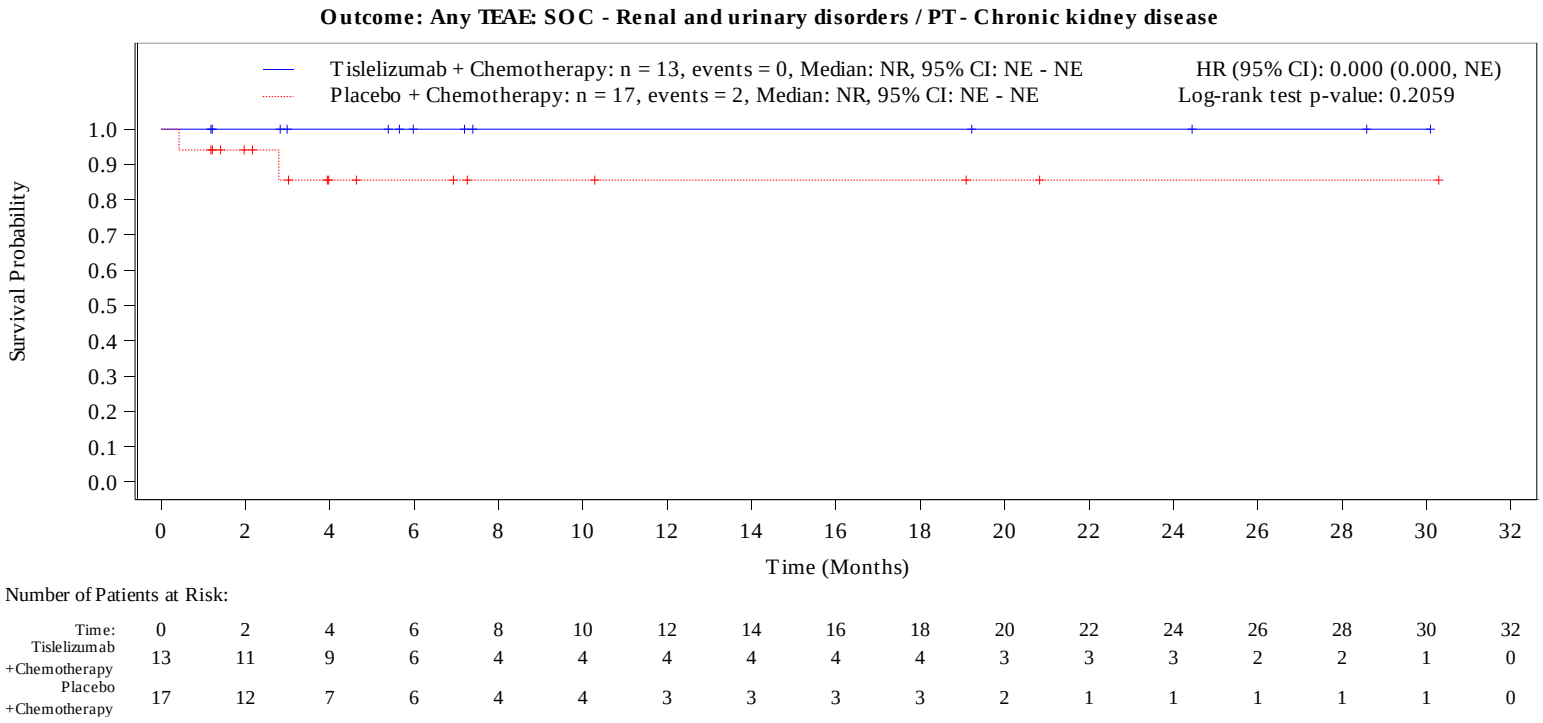

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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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Figure 14.3.1.2:
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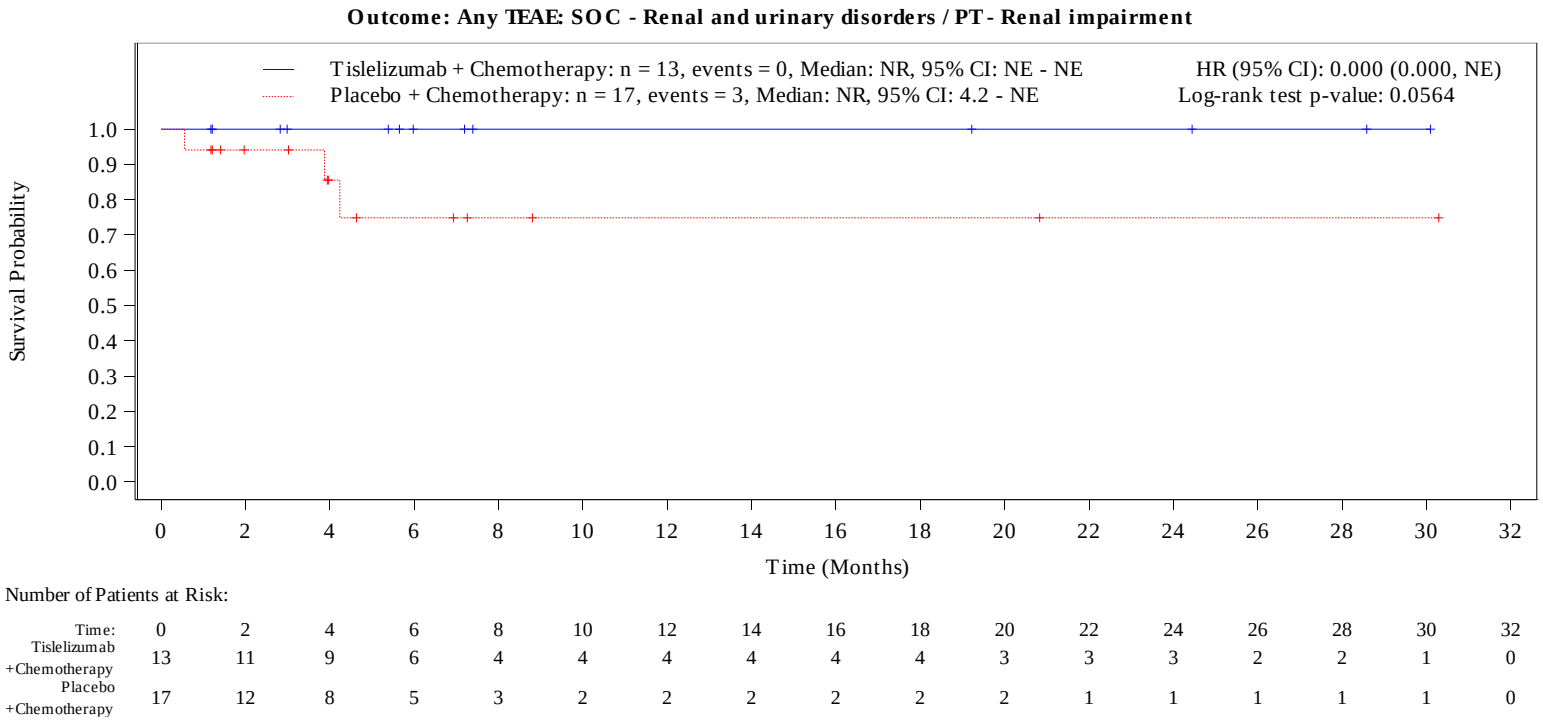

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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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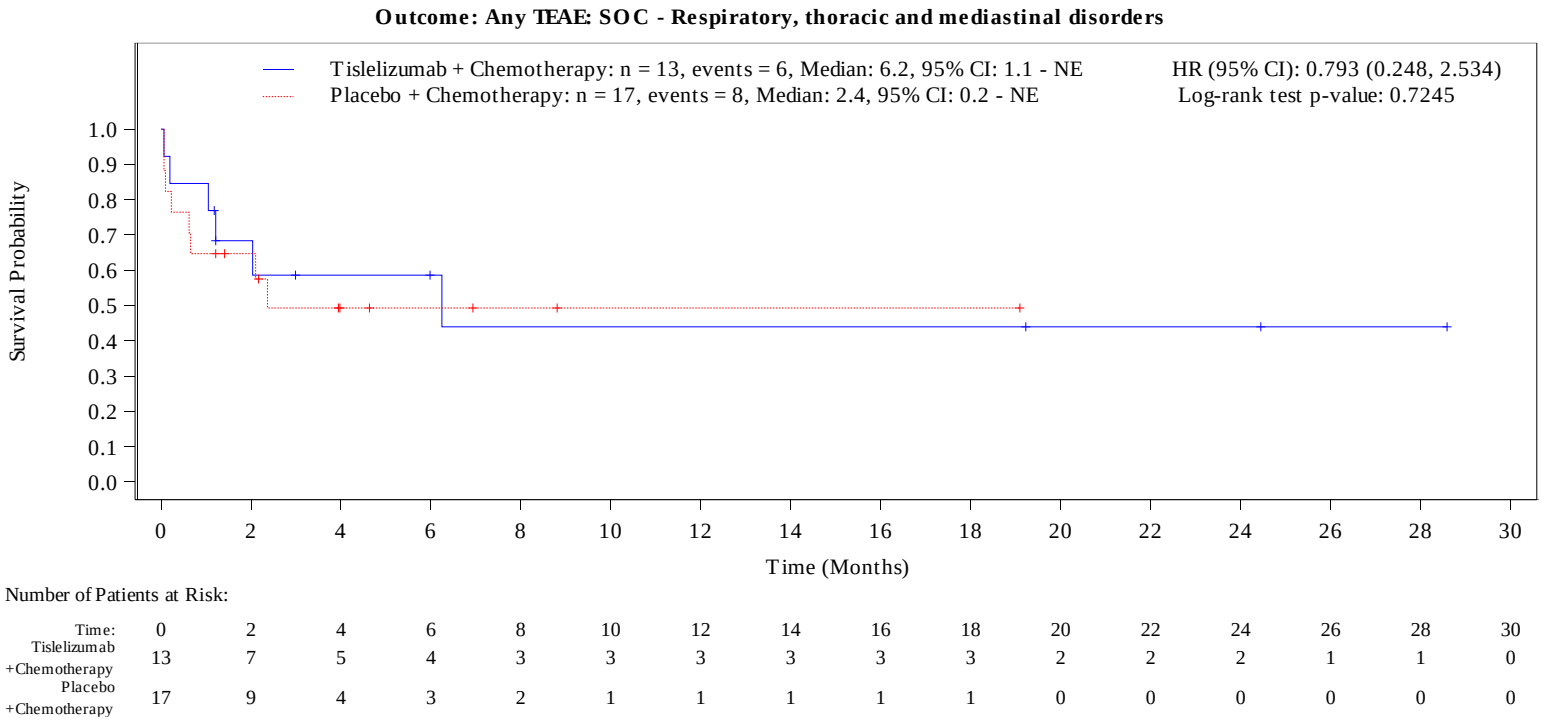

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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

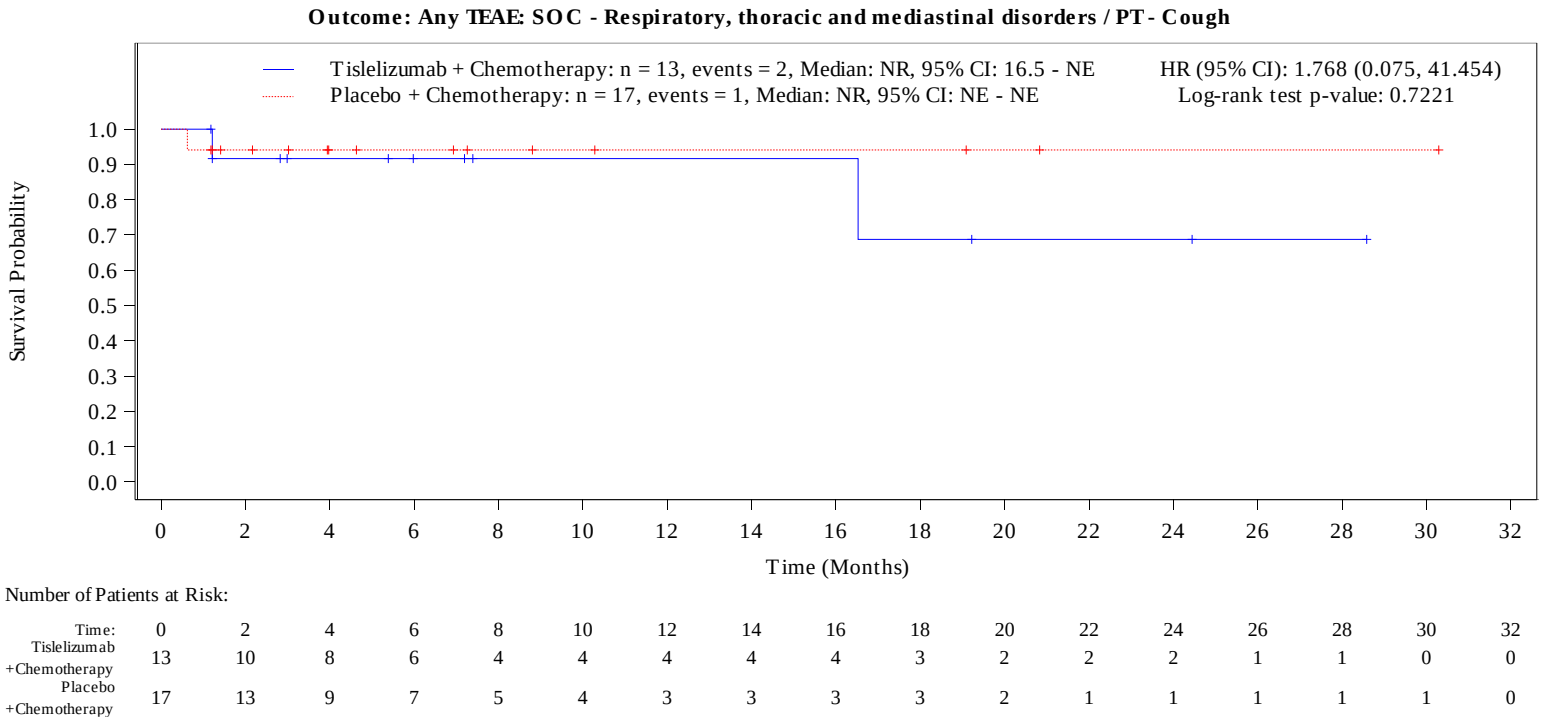

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Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

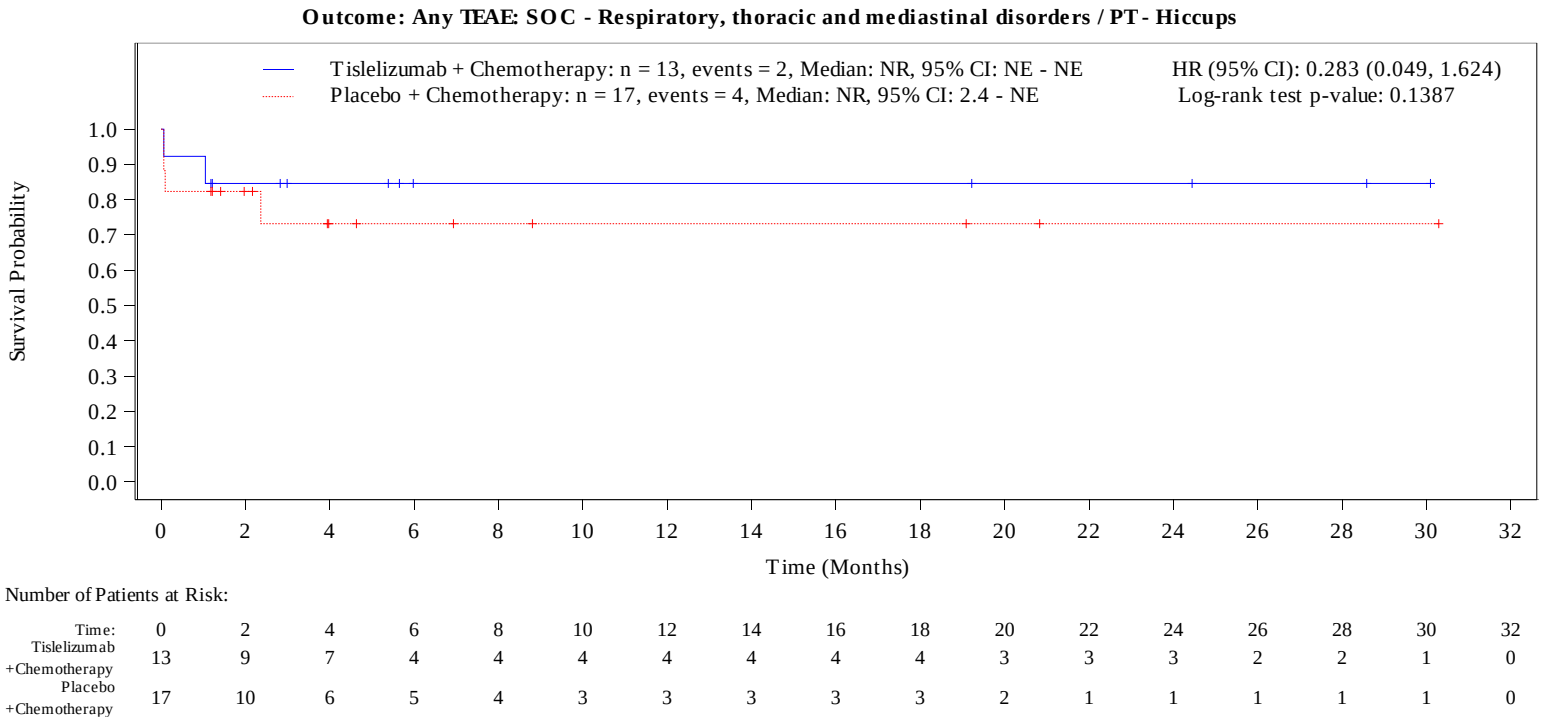

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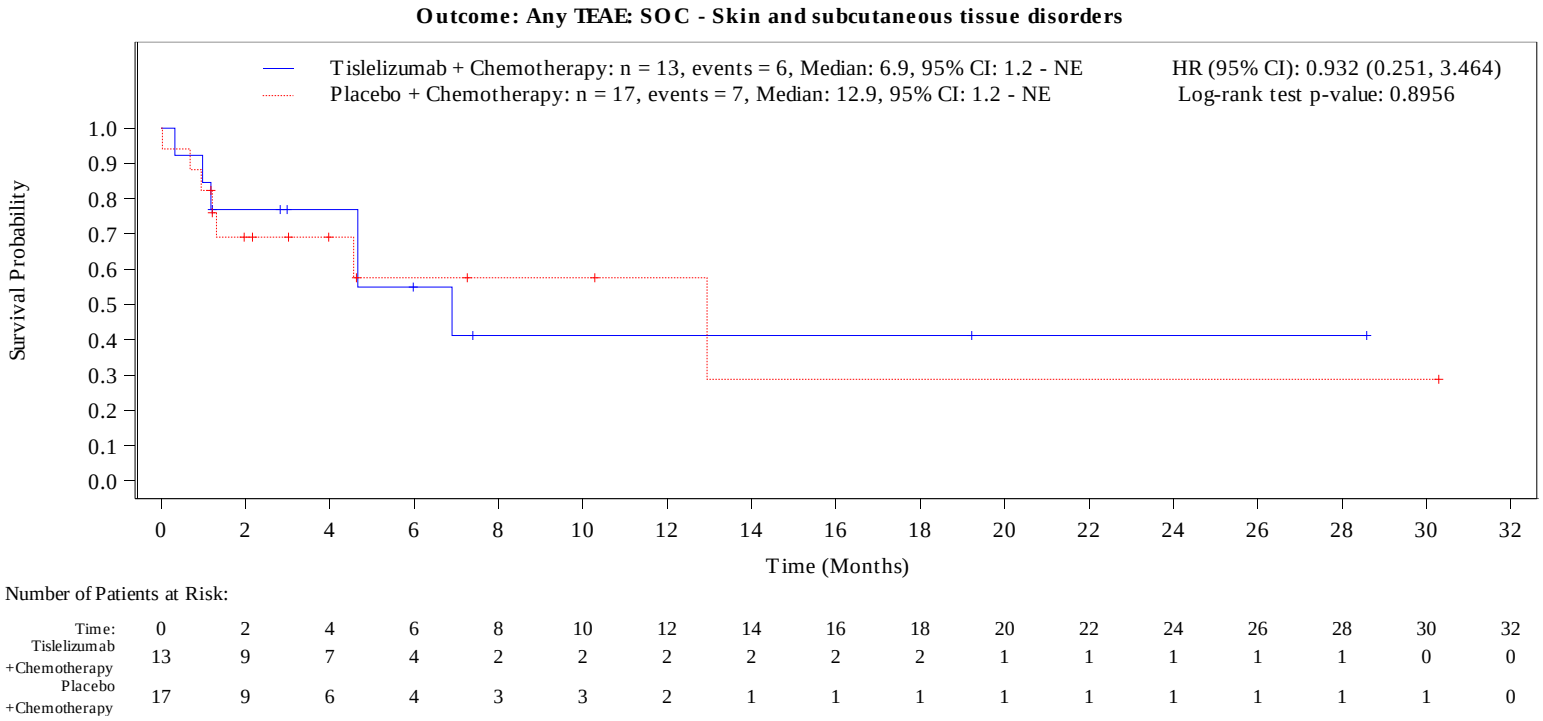
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

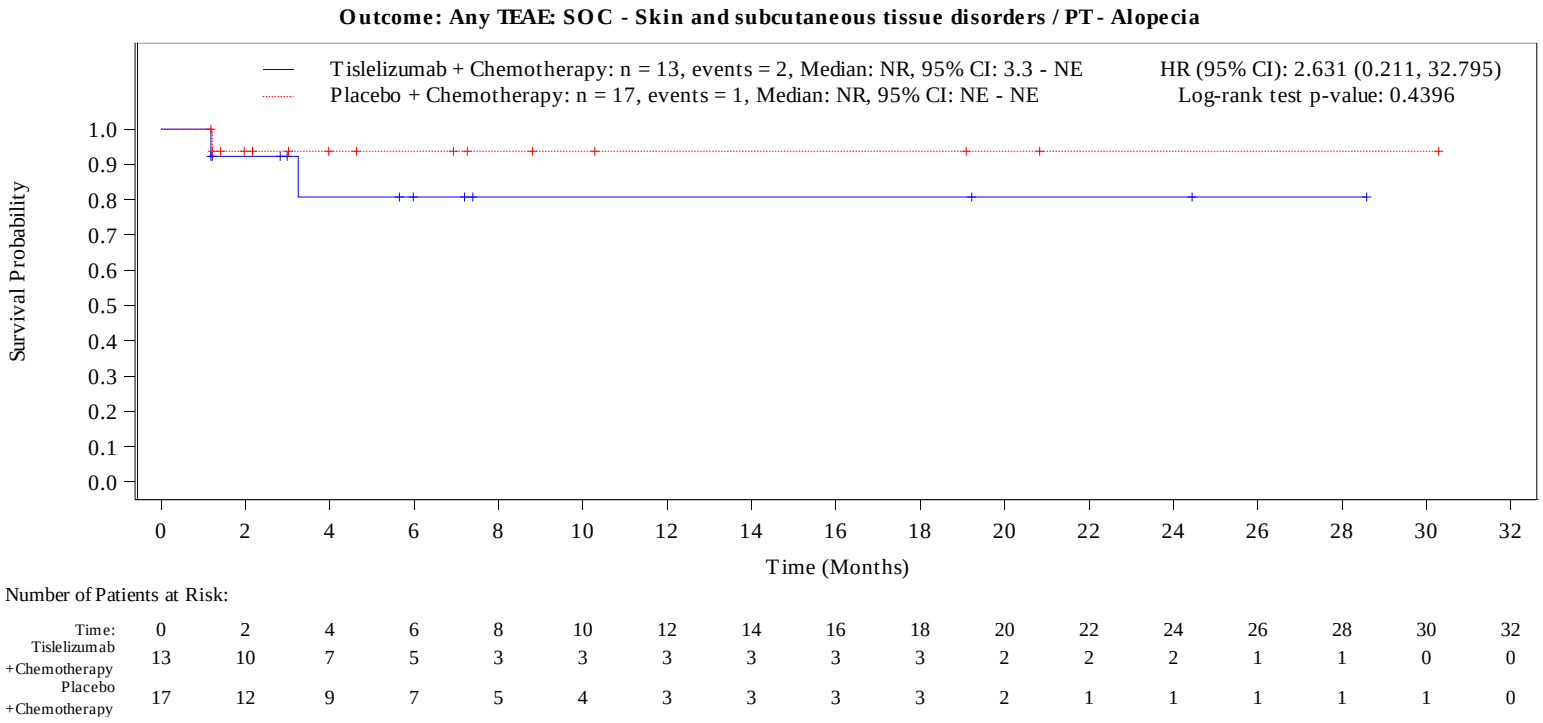

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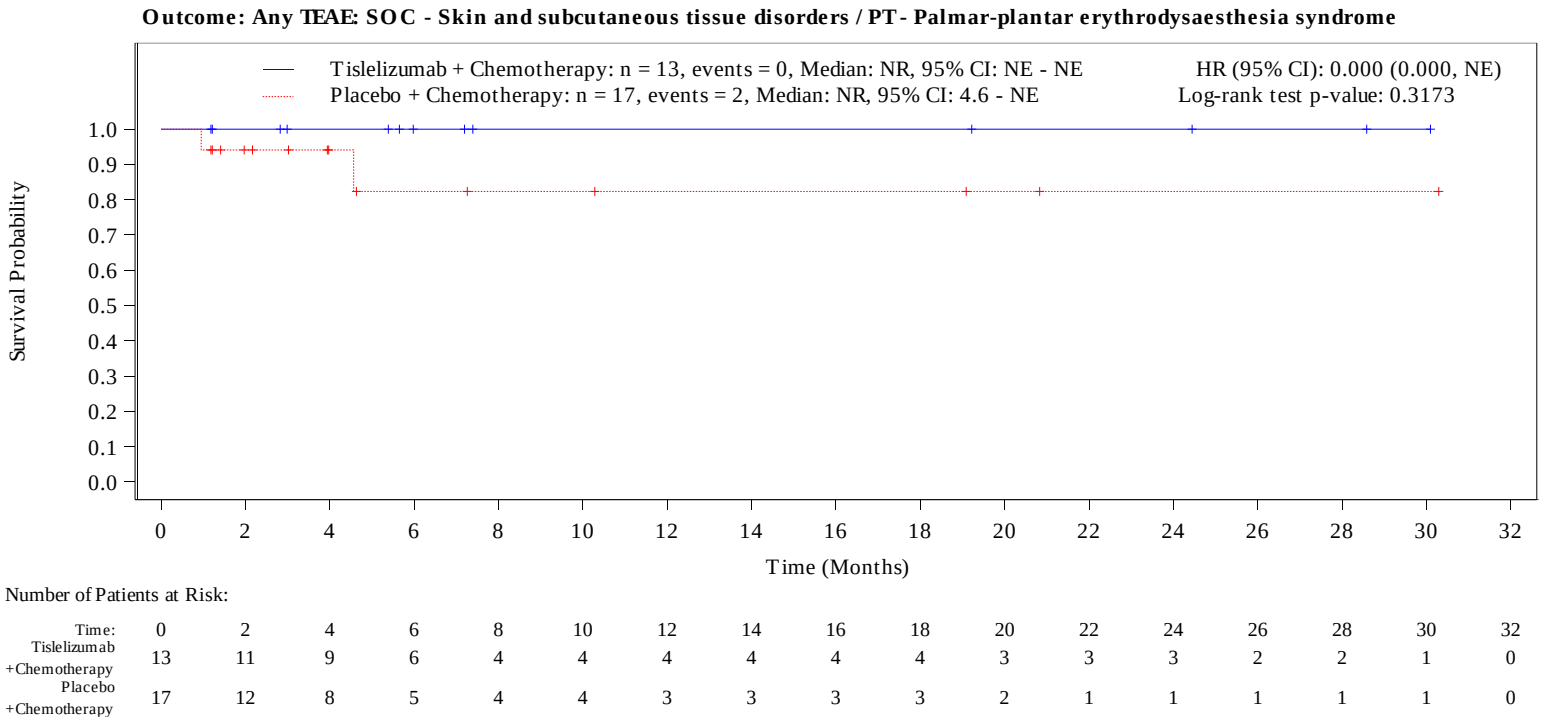
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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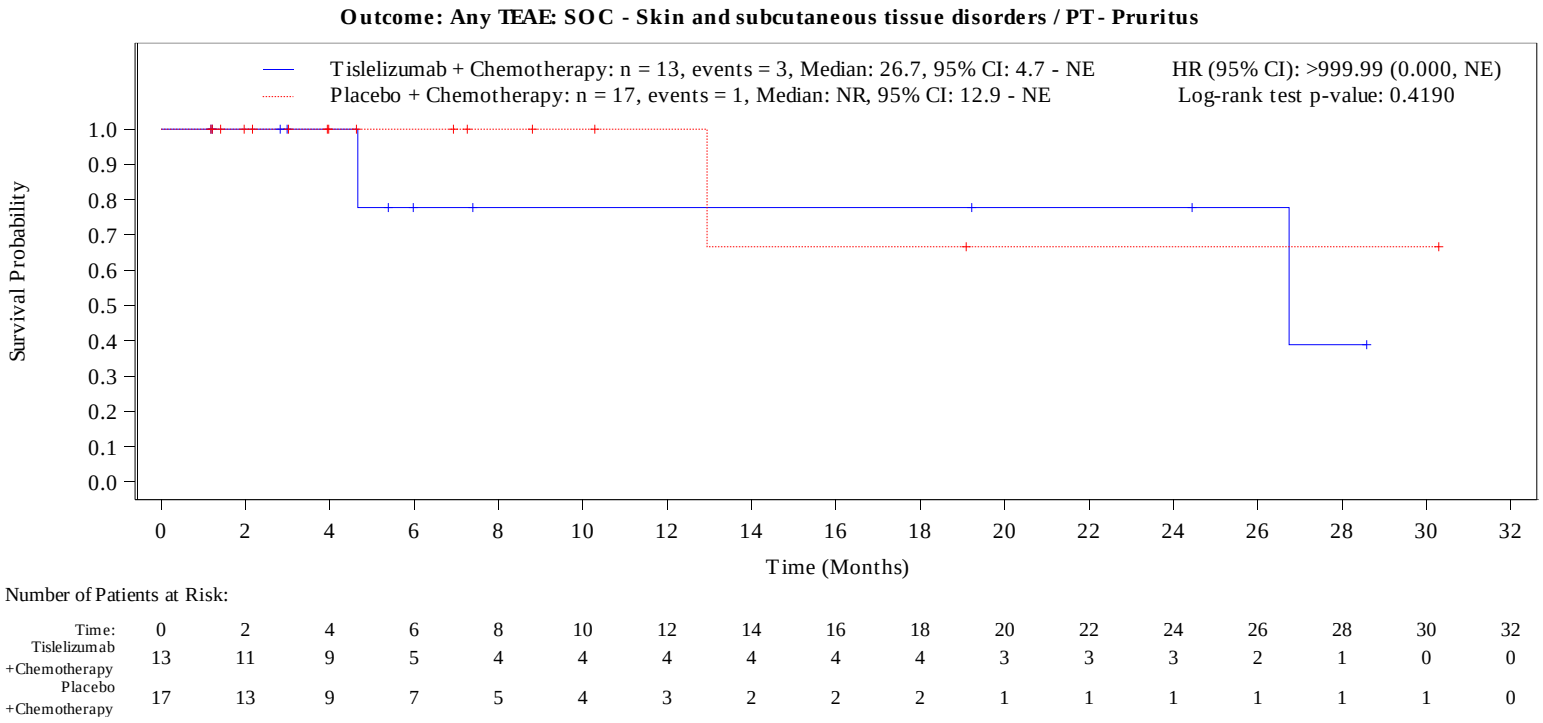
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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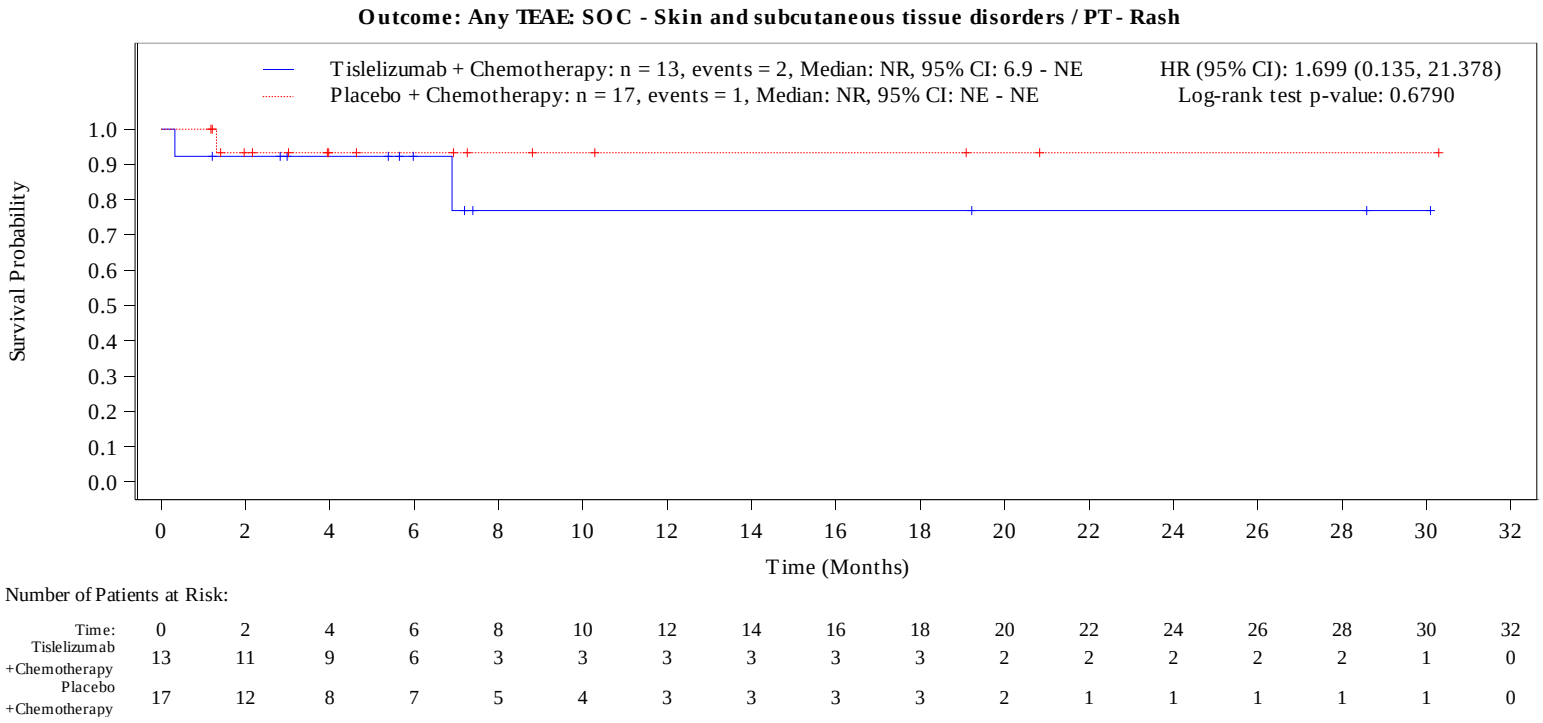
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-2-km-aesocpt-teae-pop1-ia.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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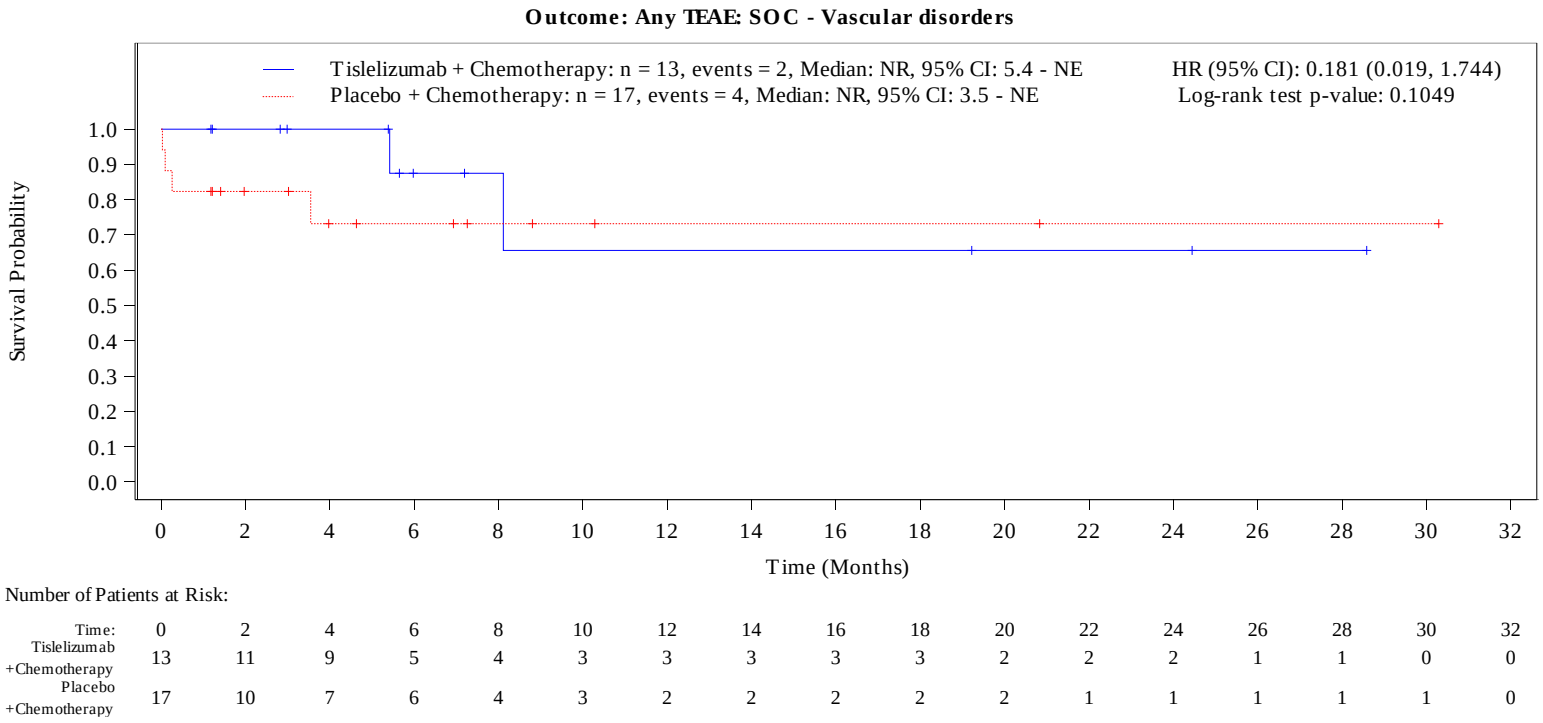
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

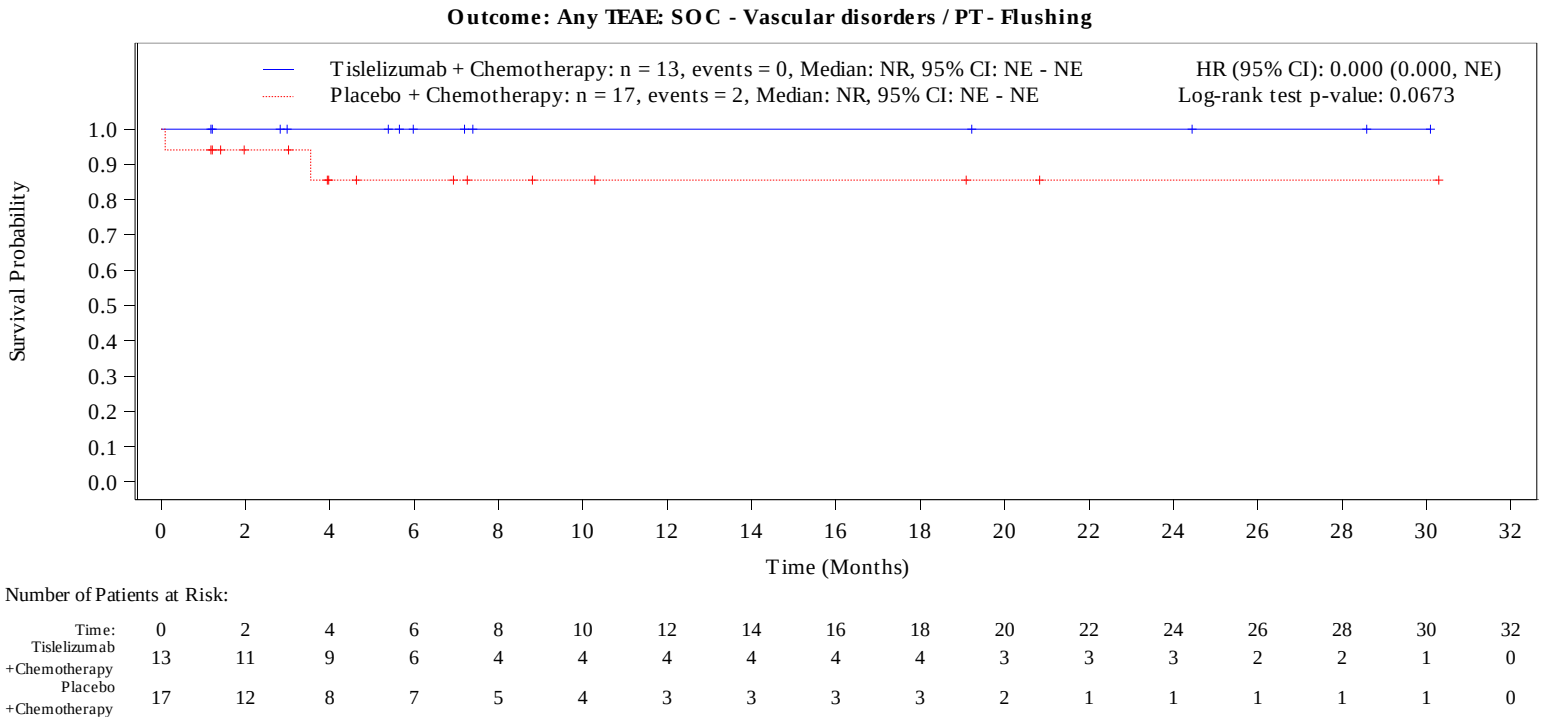

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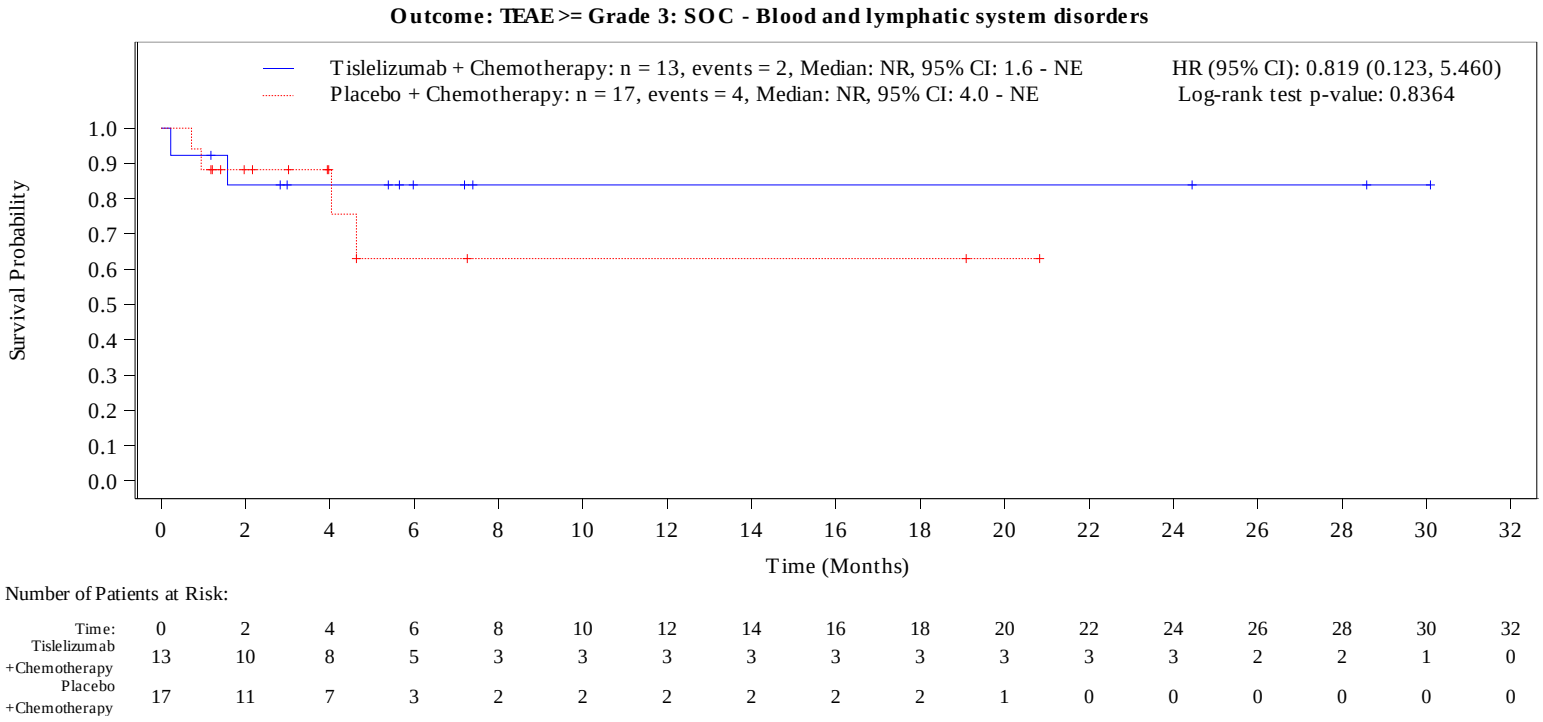
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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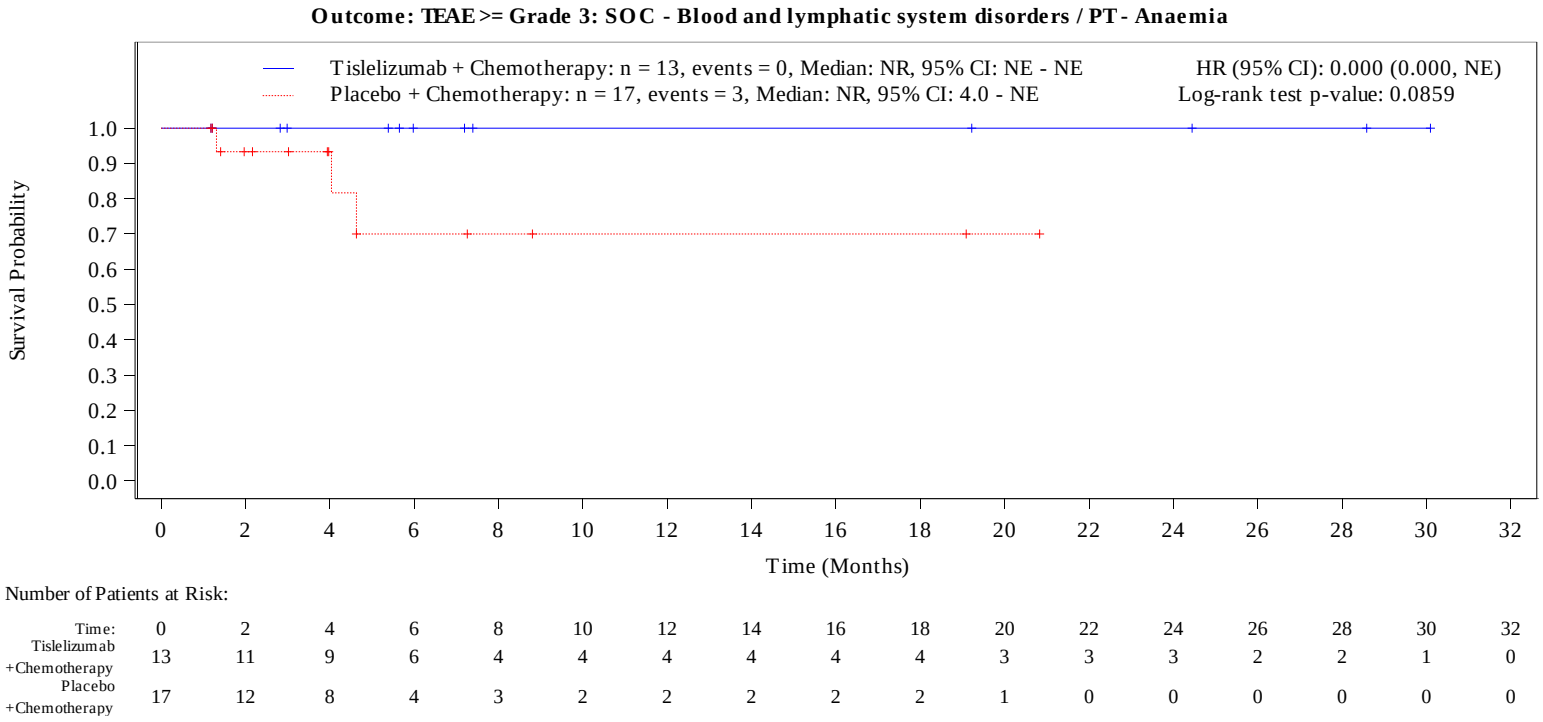
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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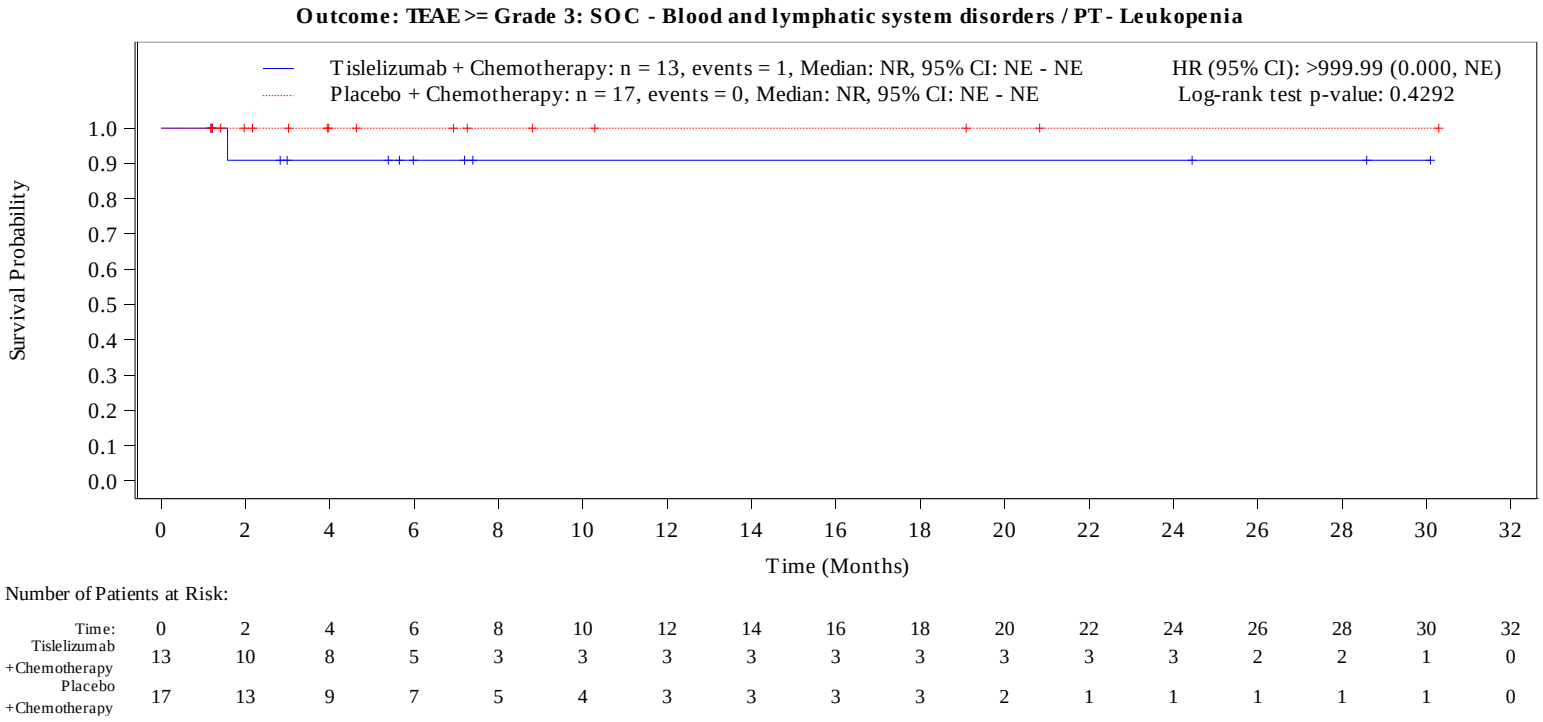

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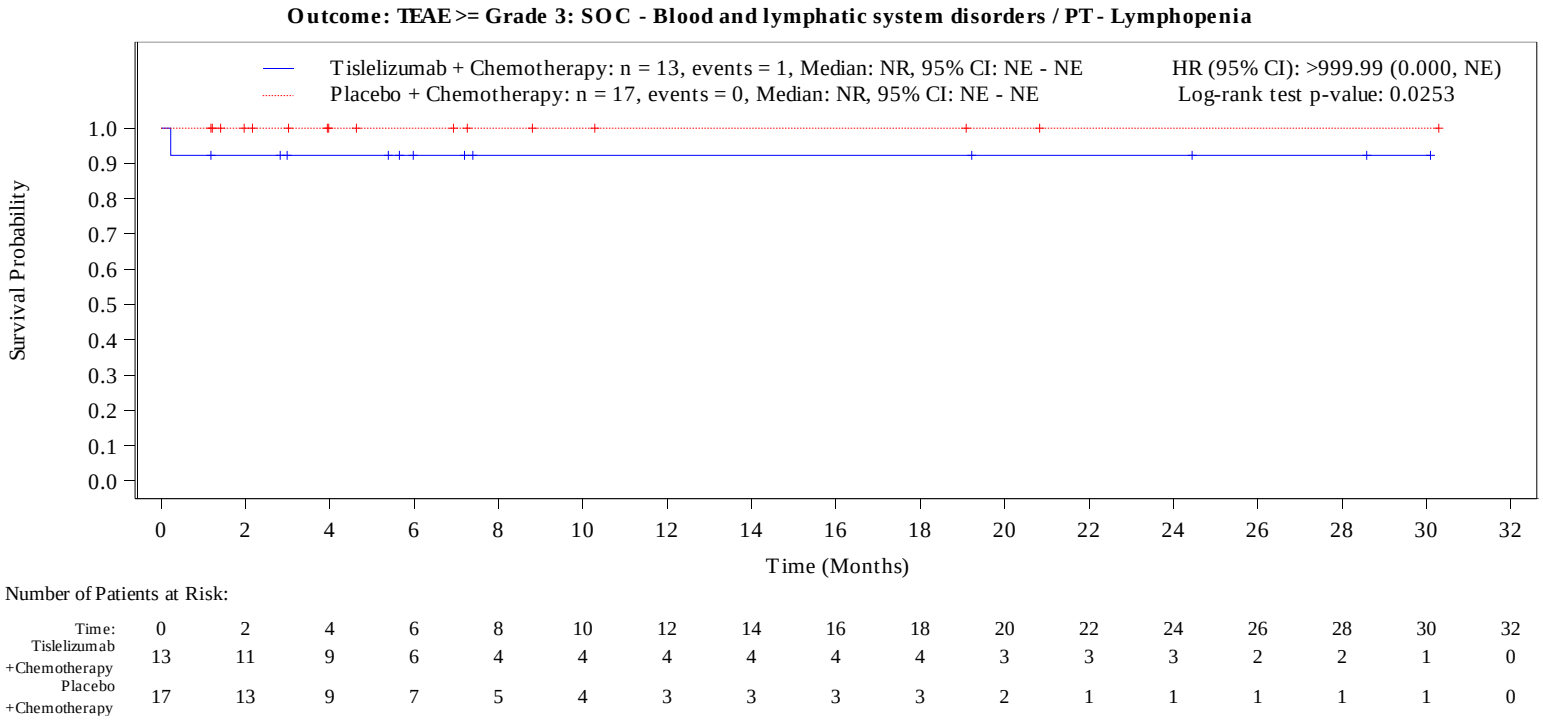

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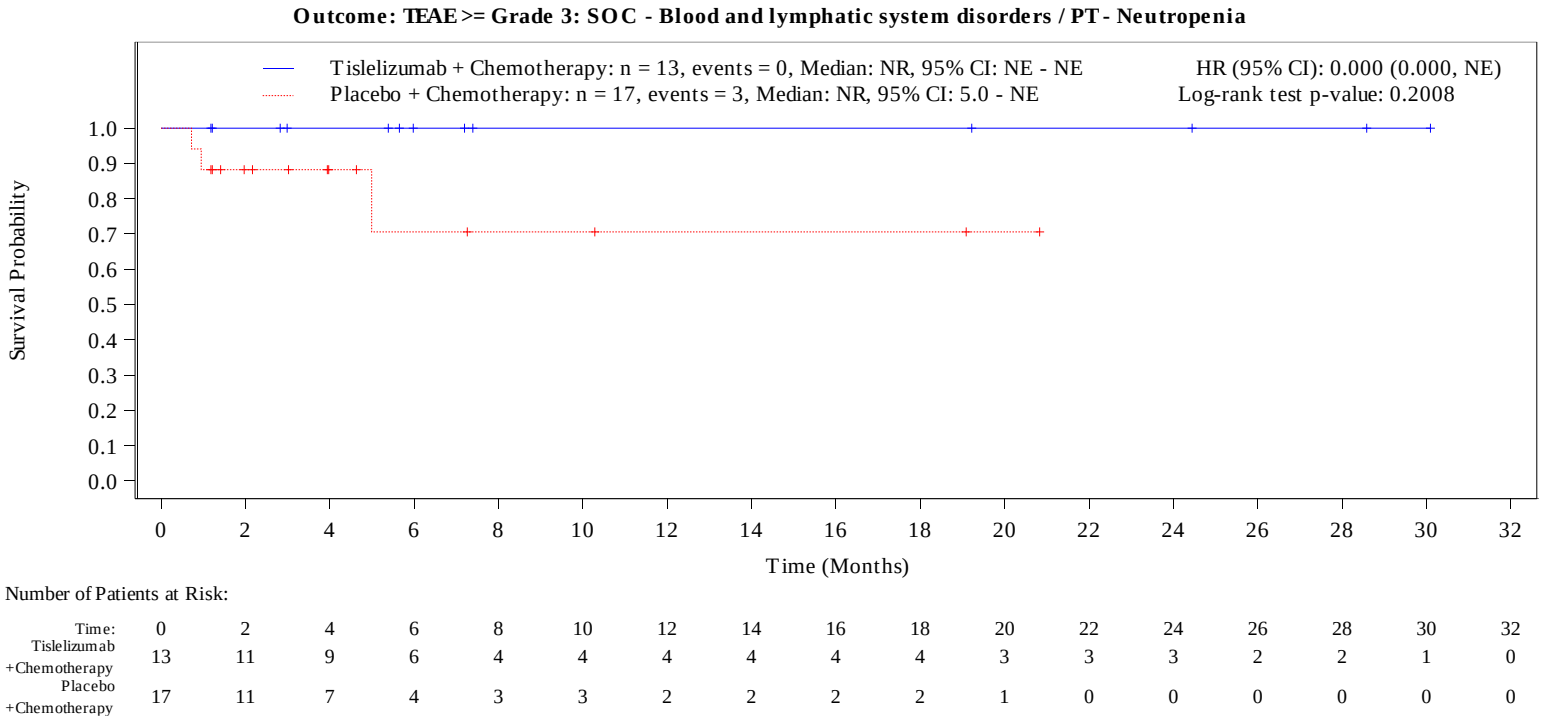

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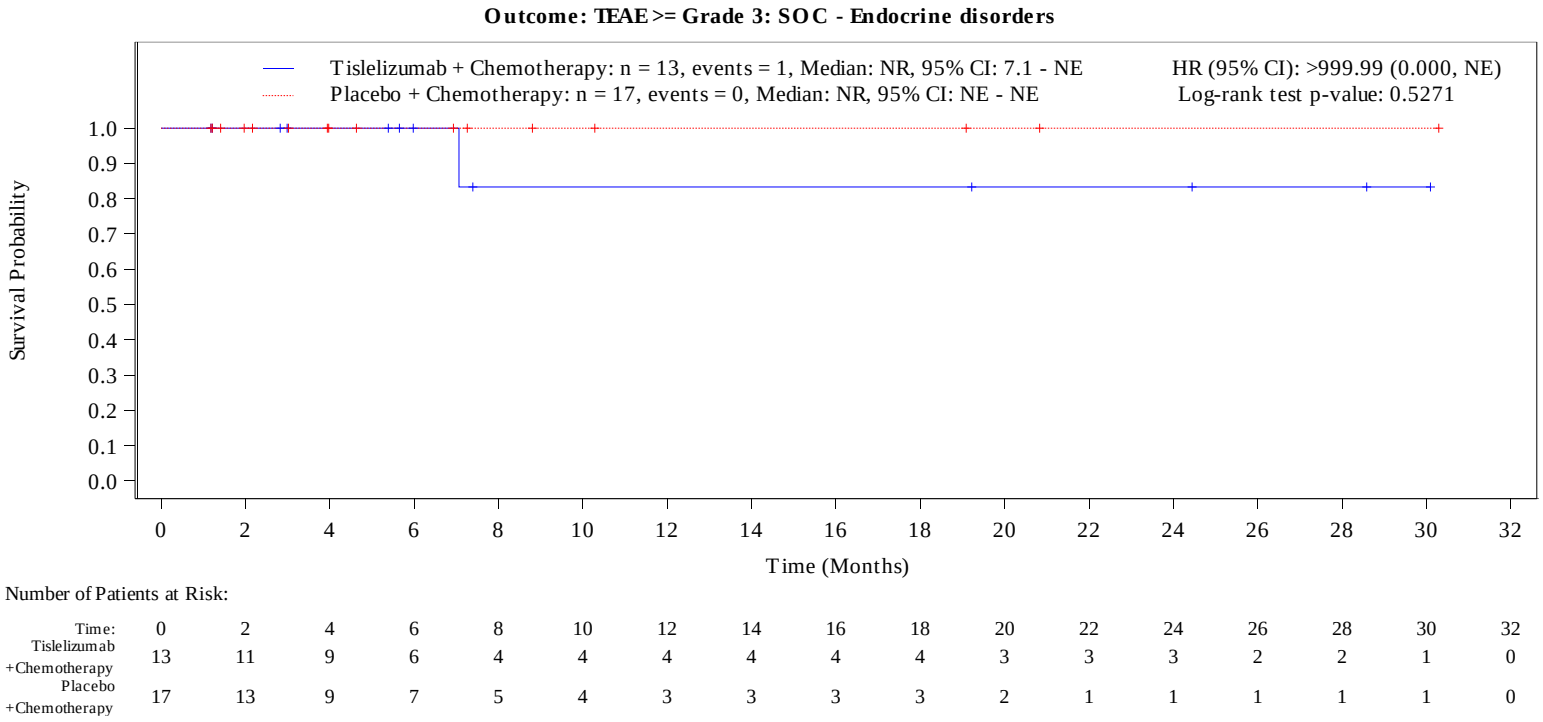

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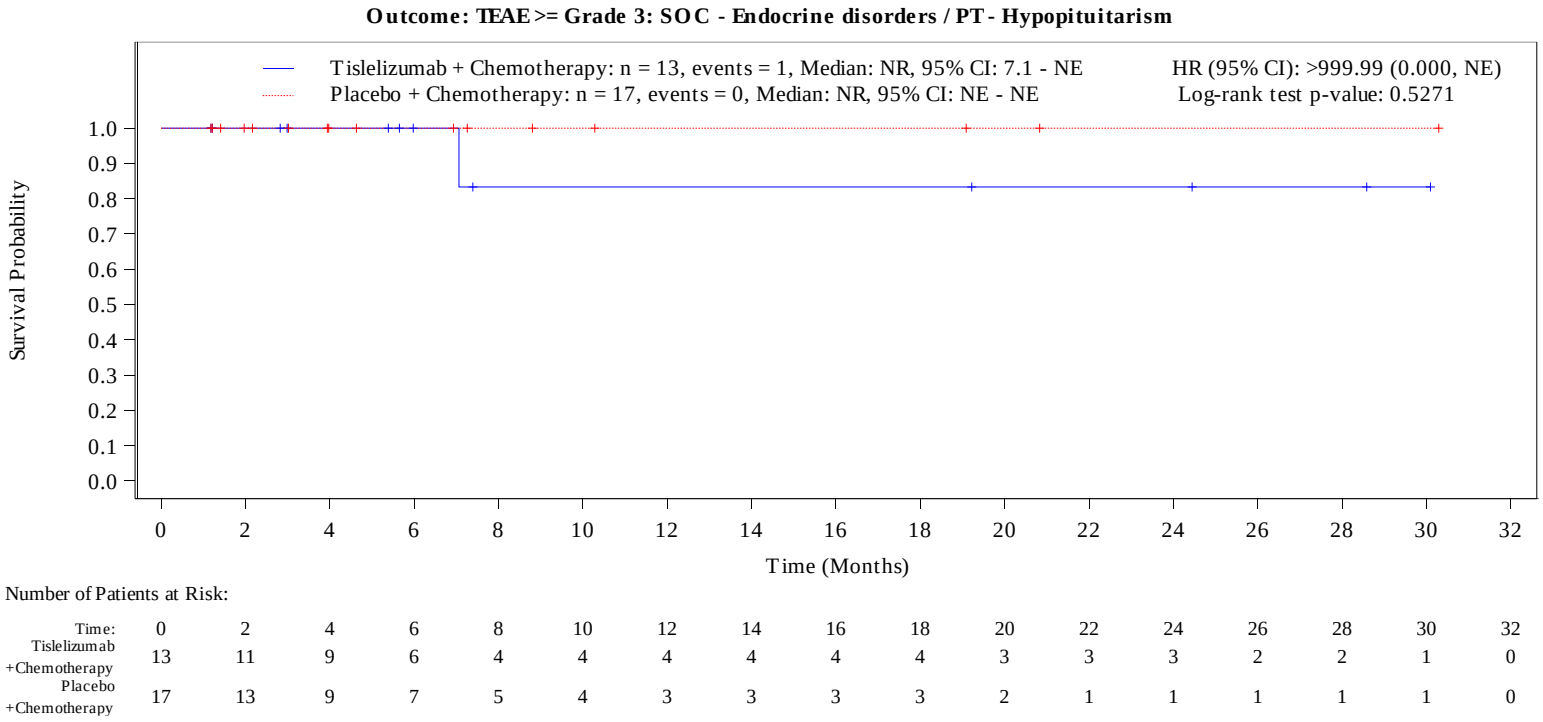

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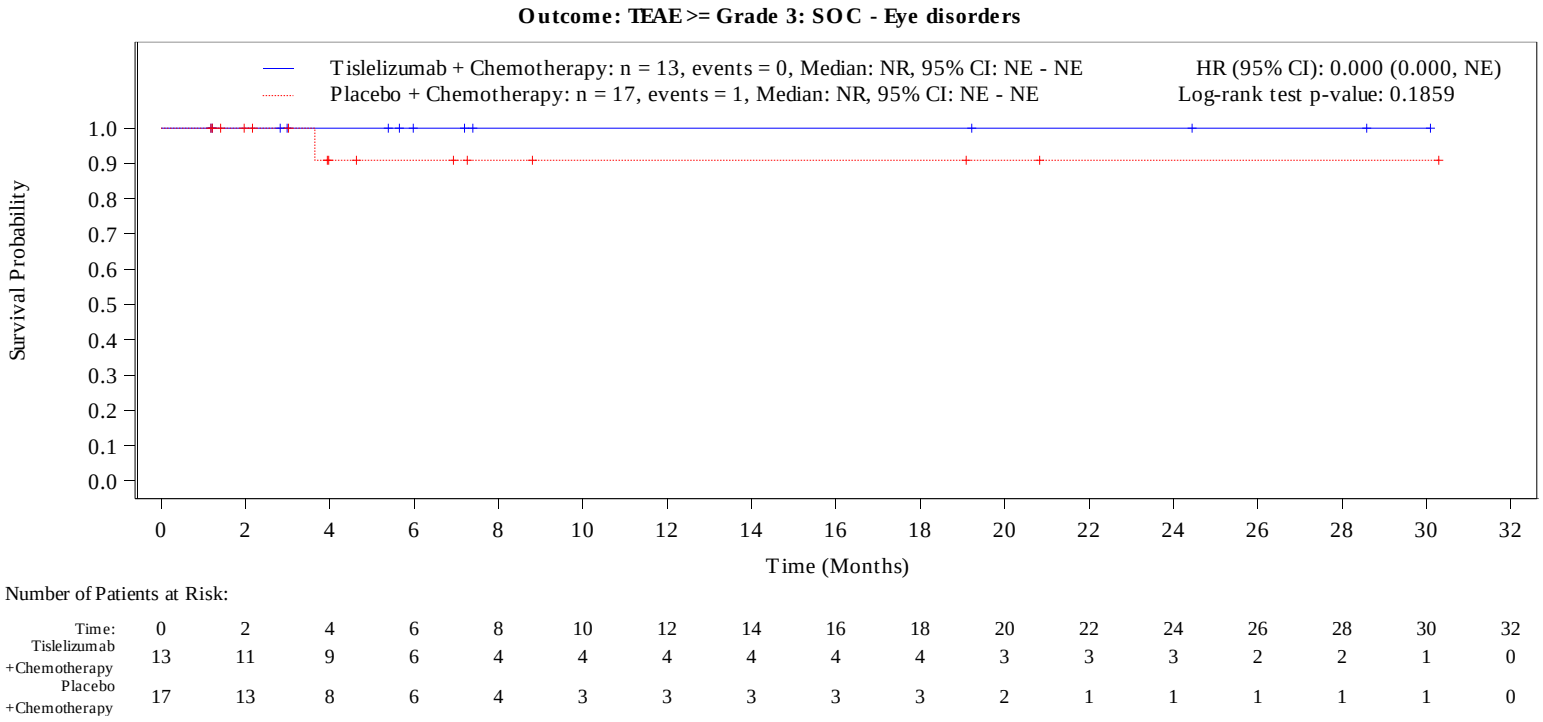

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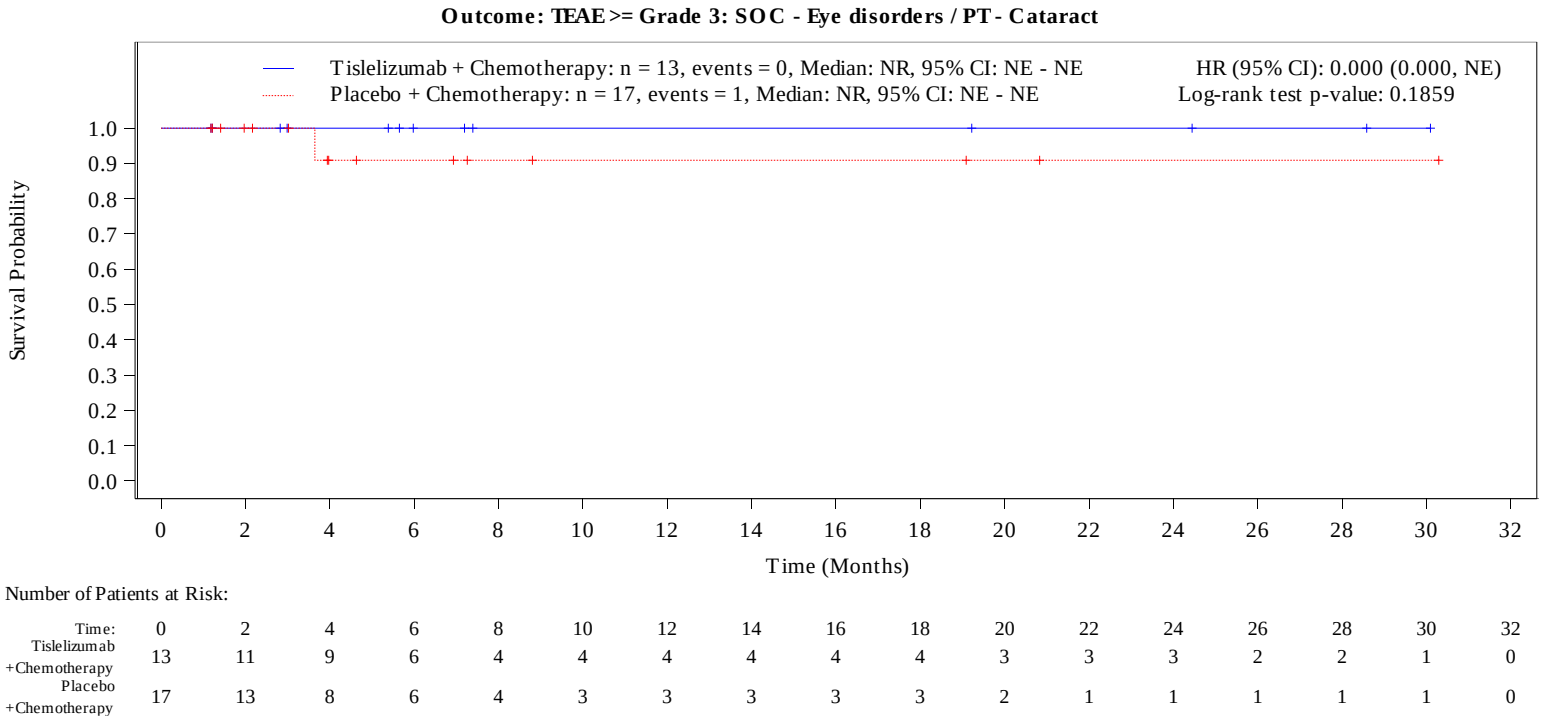

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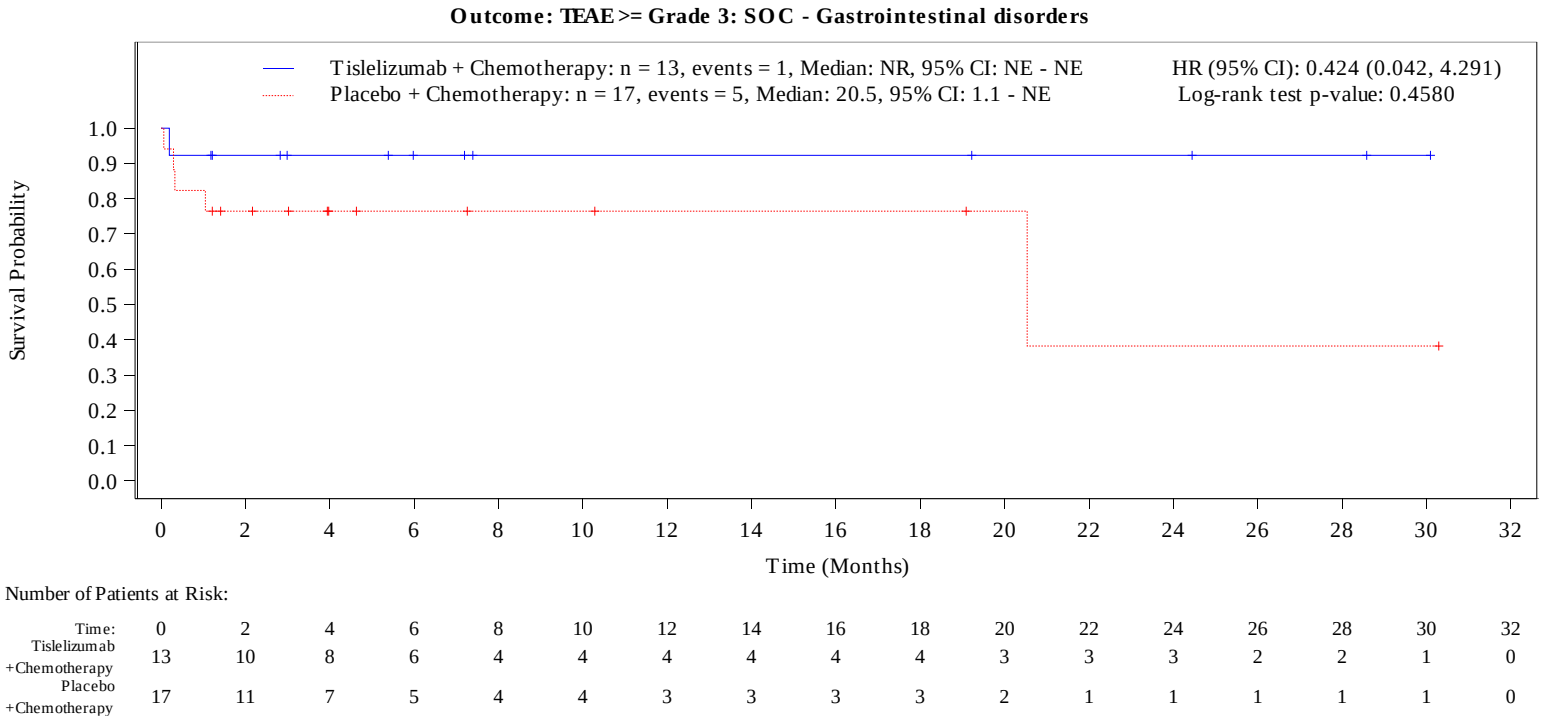

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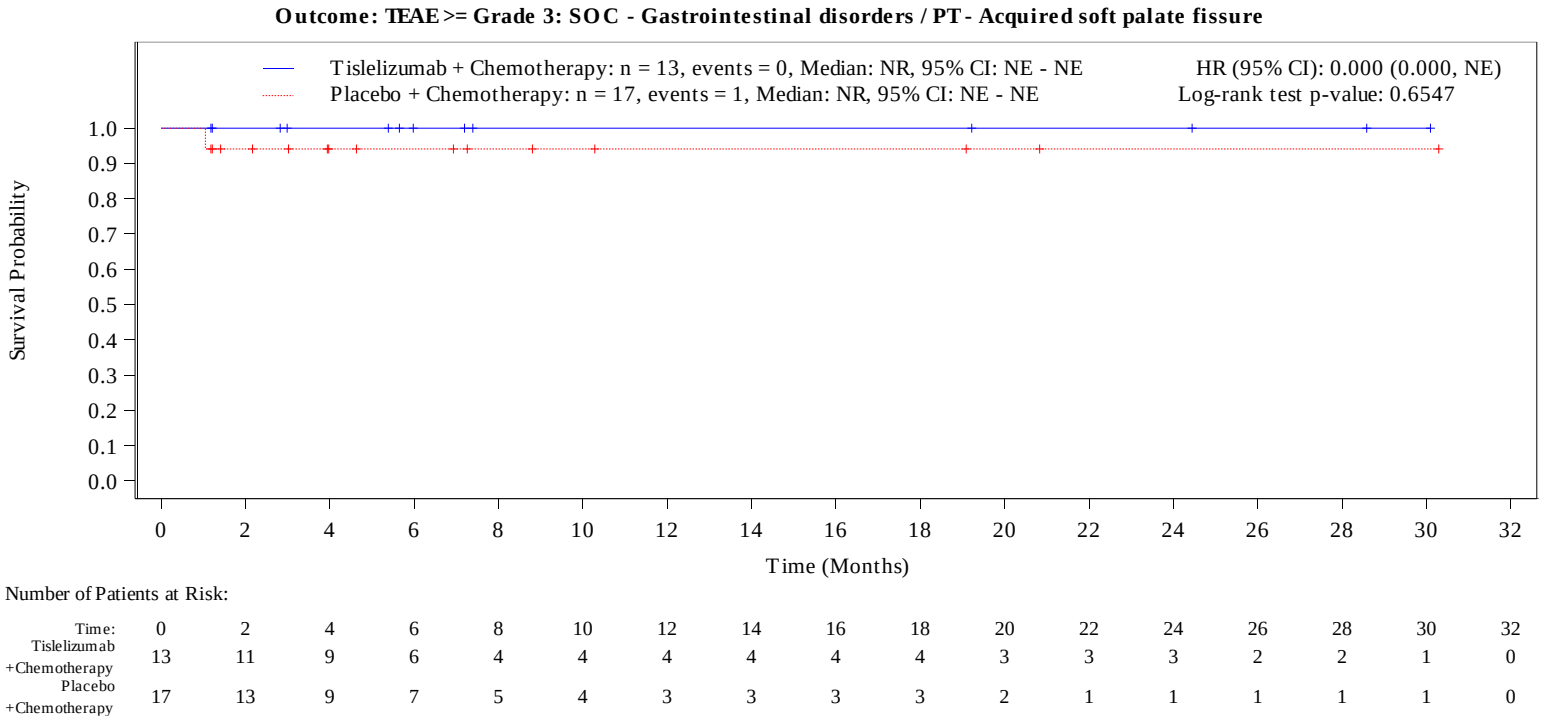

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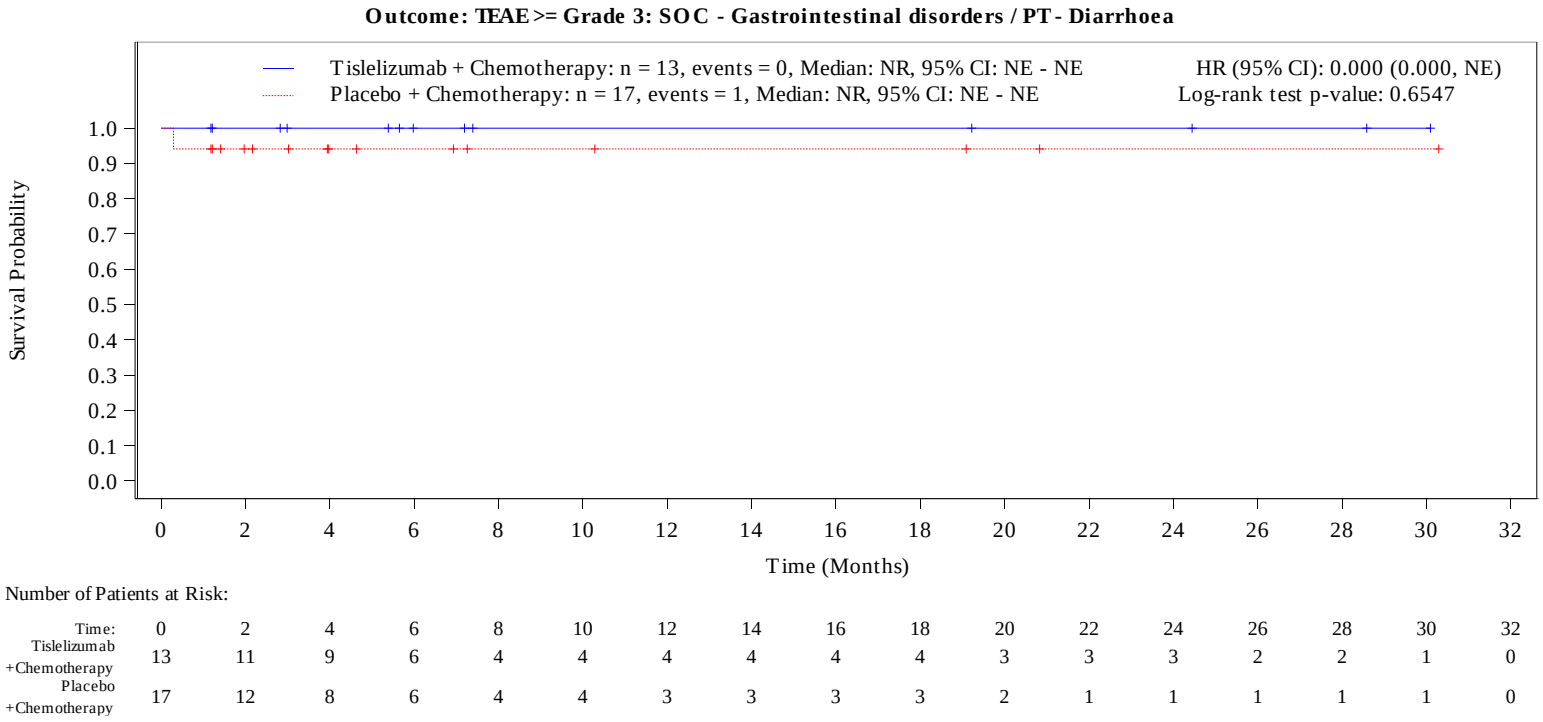

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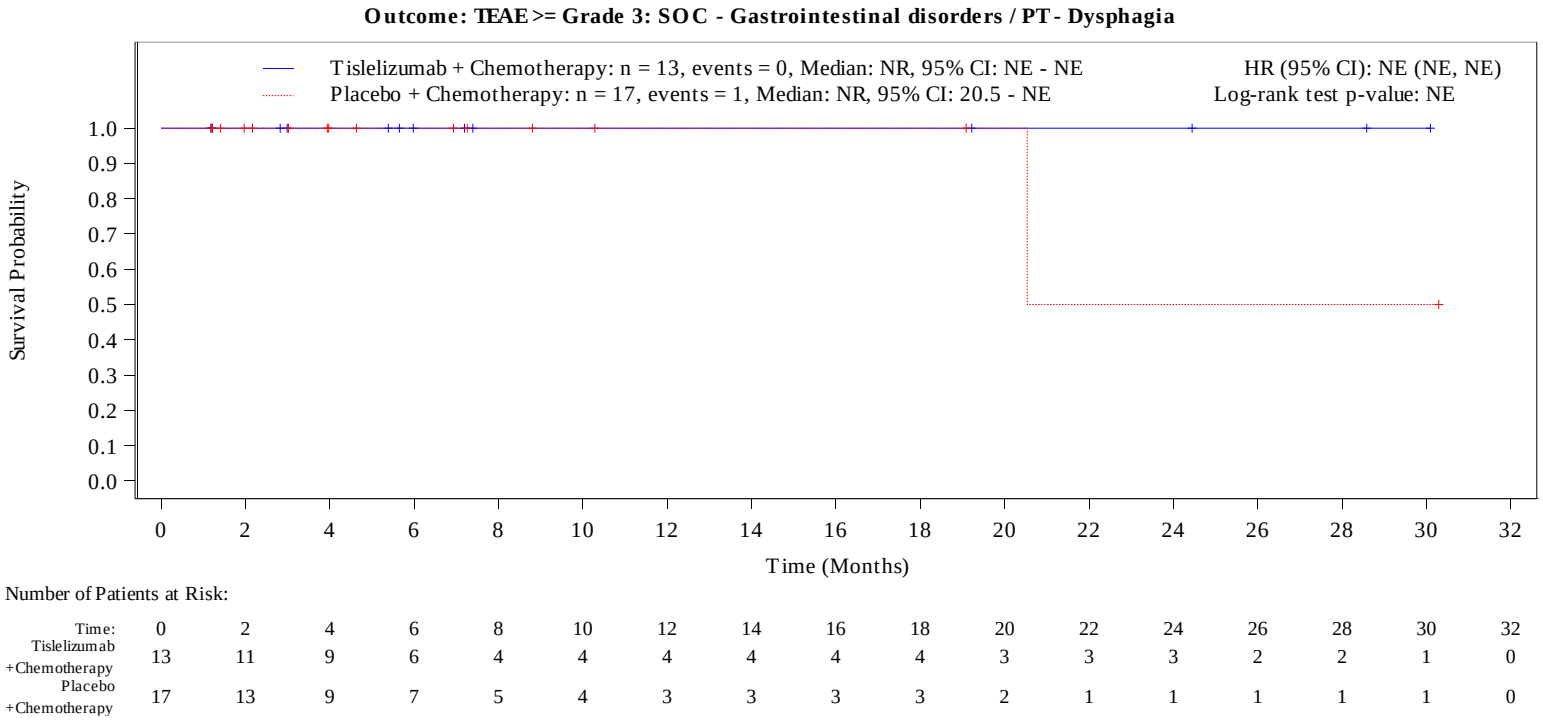

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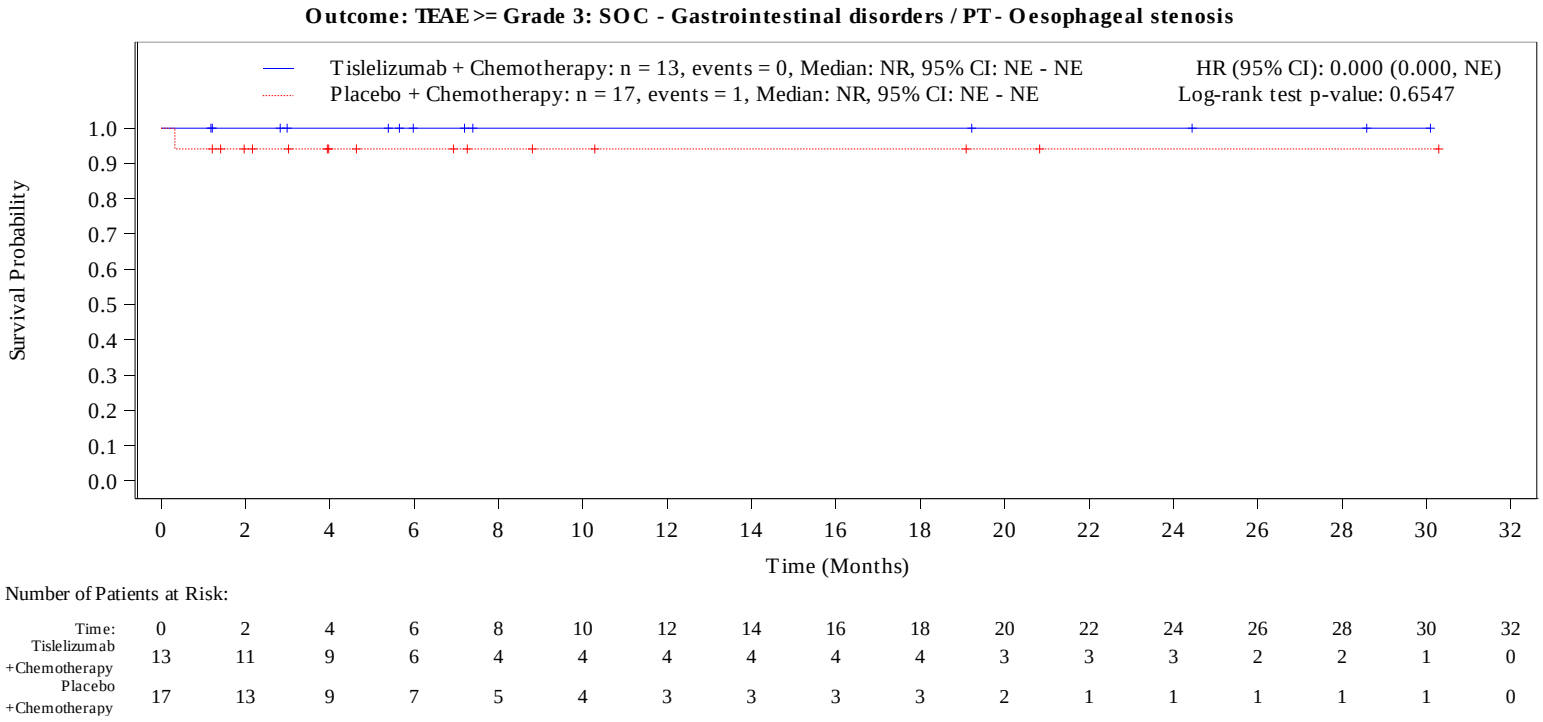

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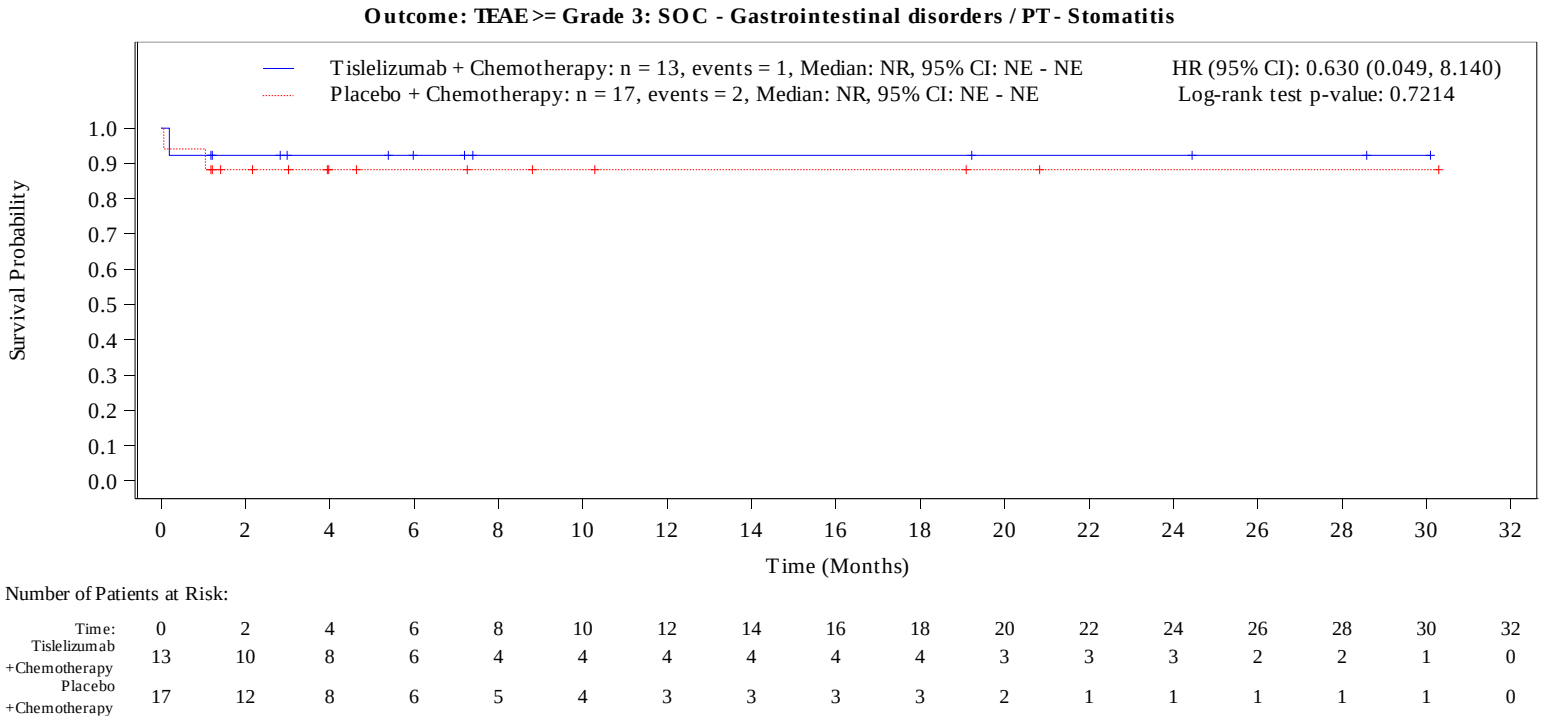

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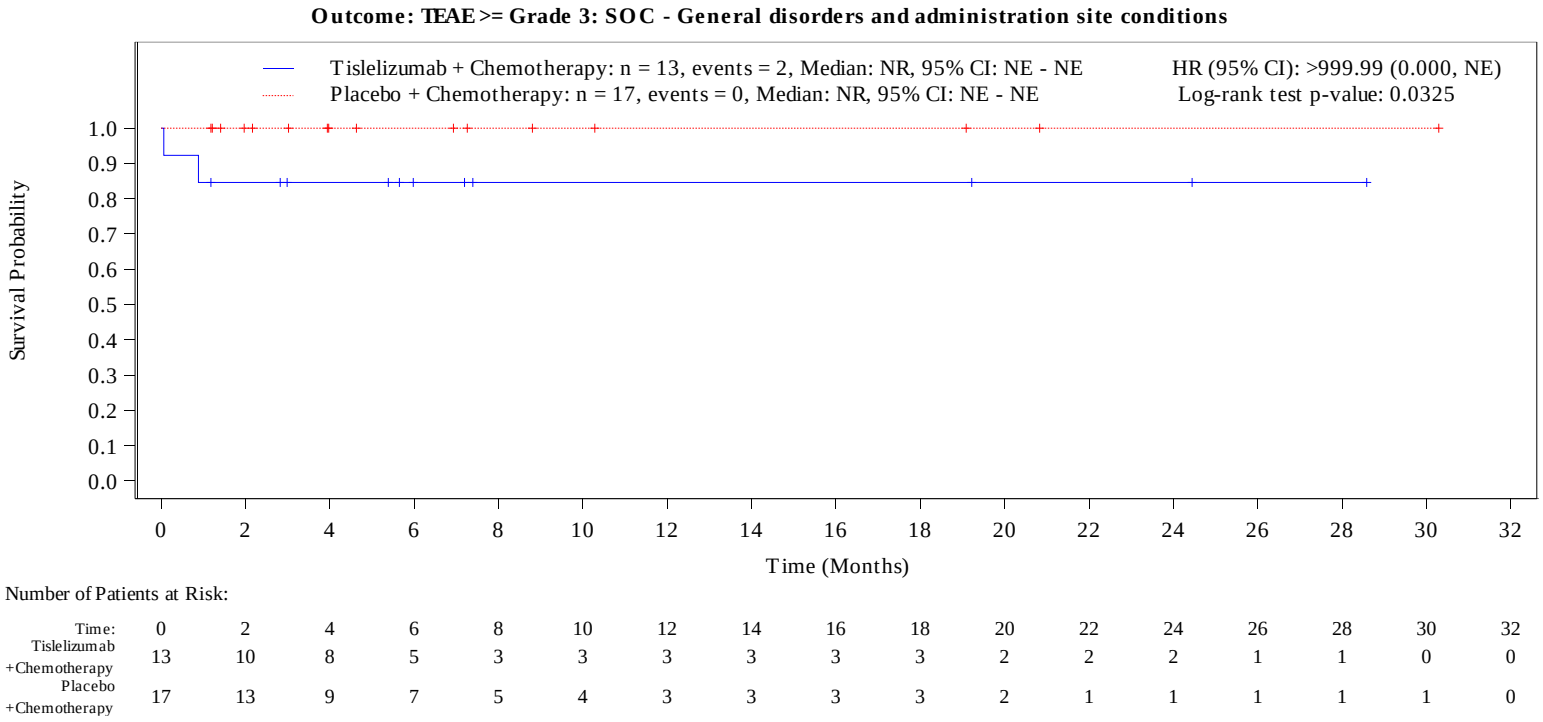

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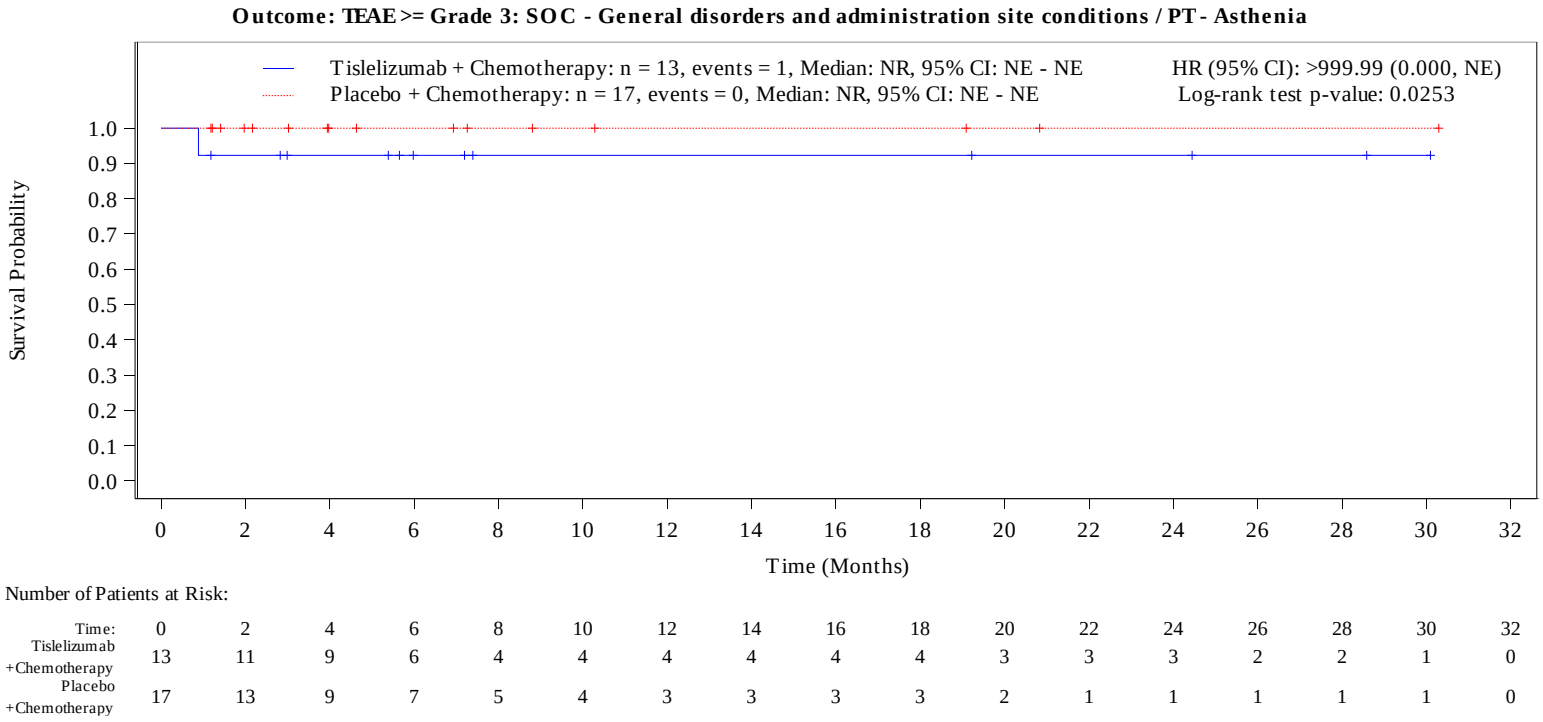

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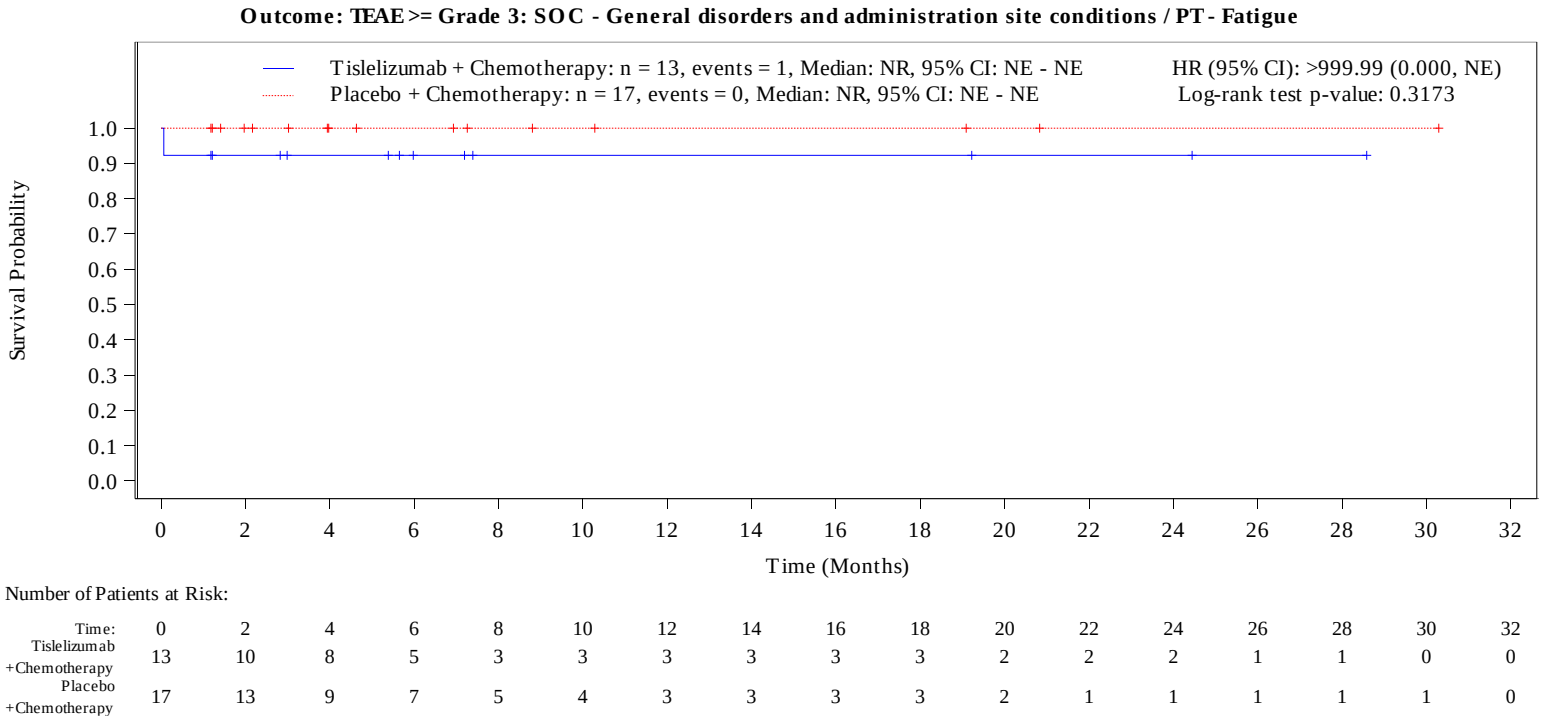

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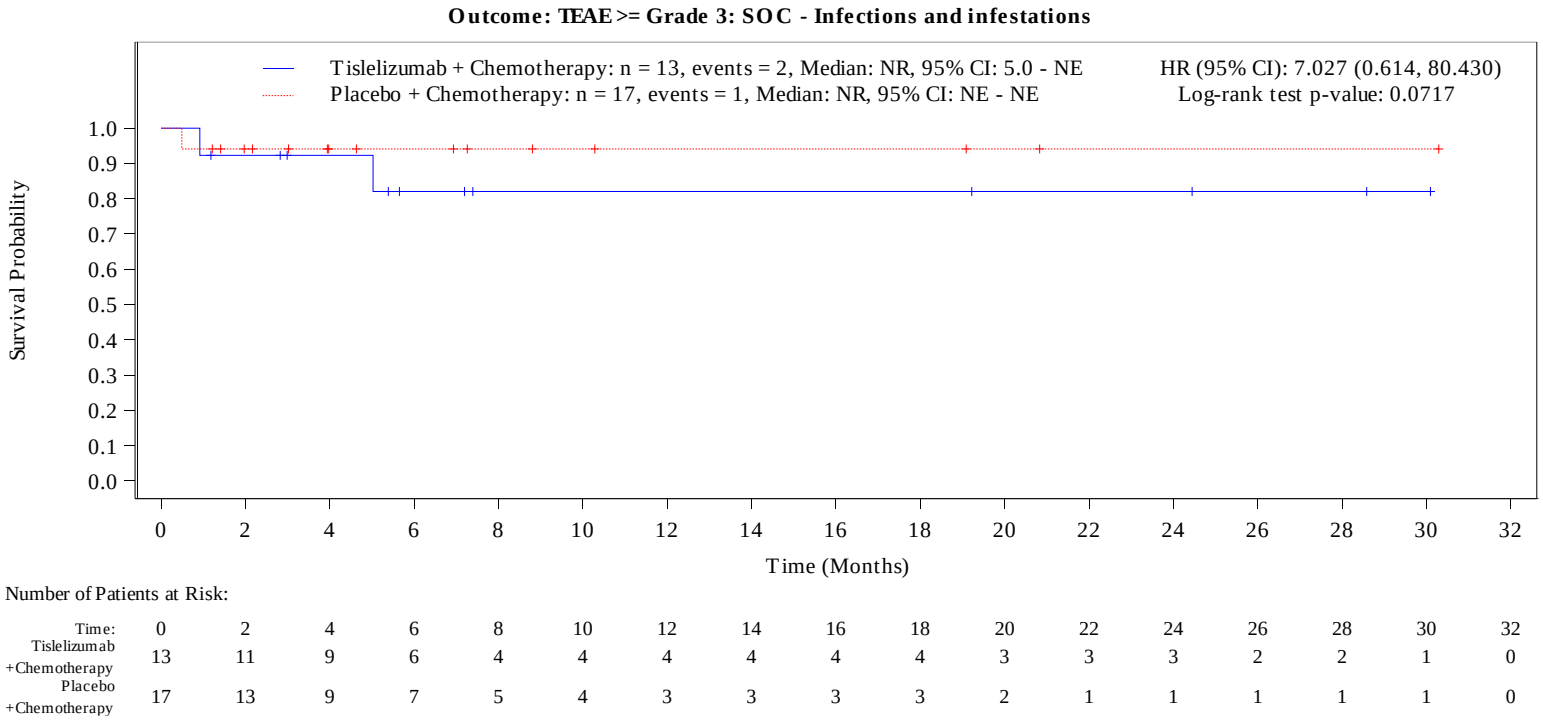

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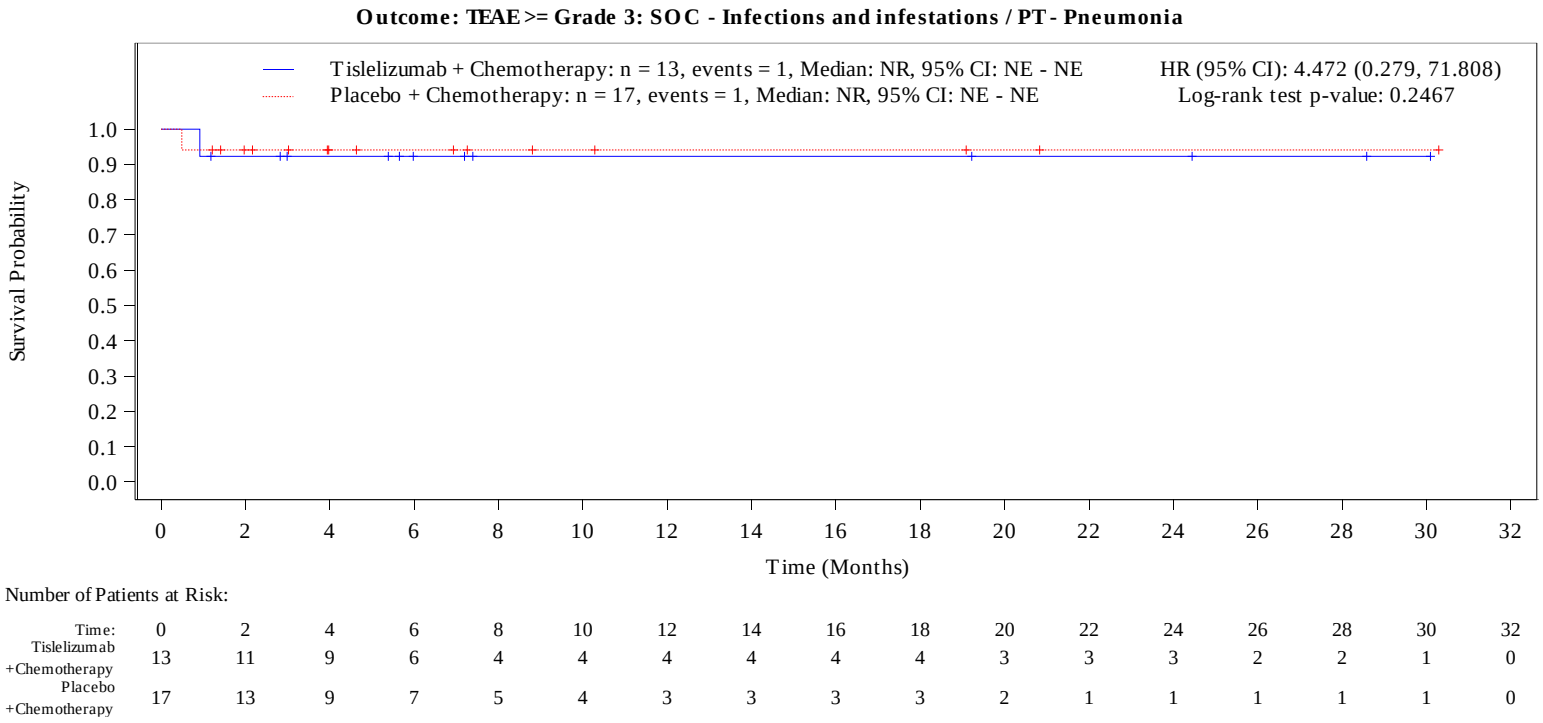

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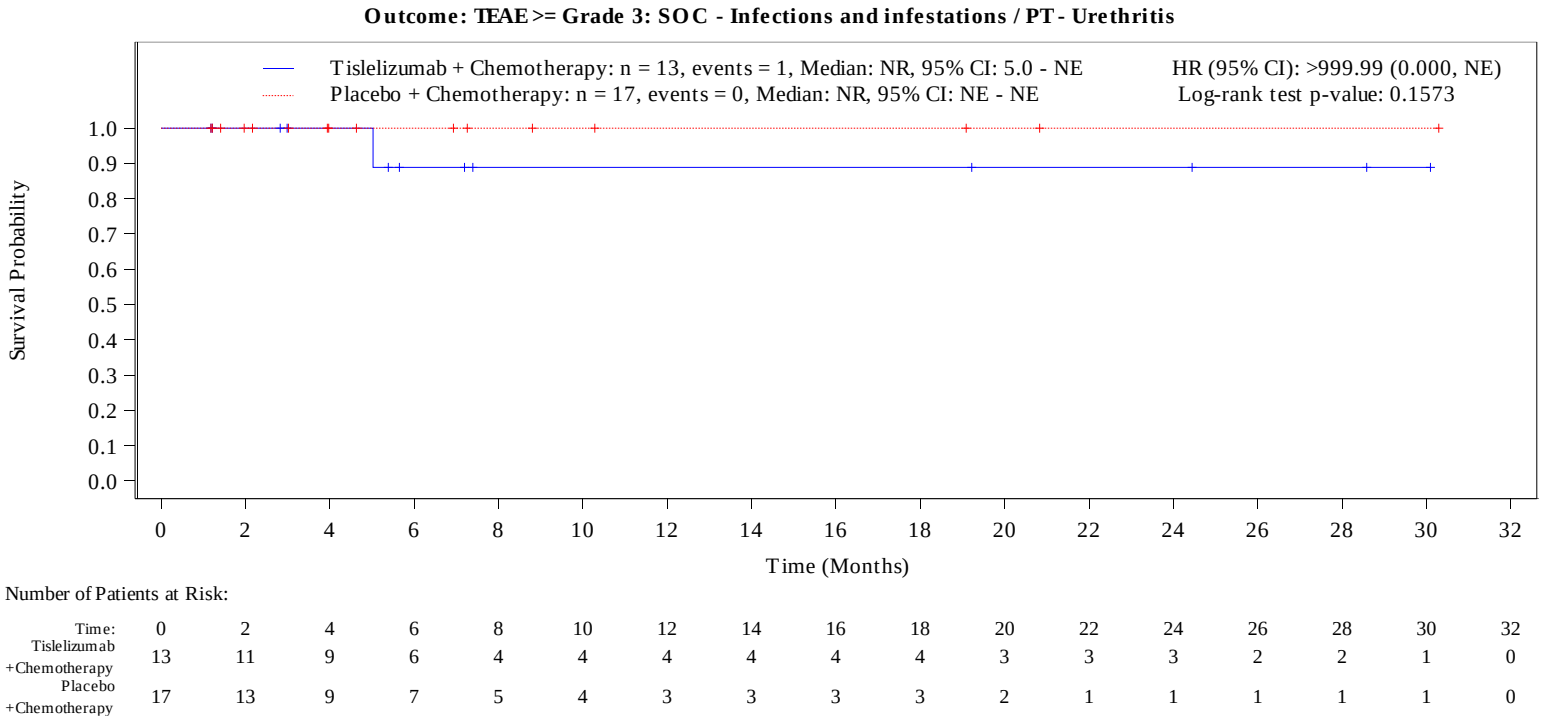
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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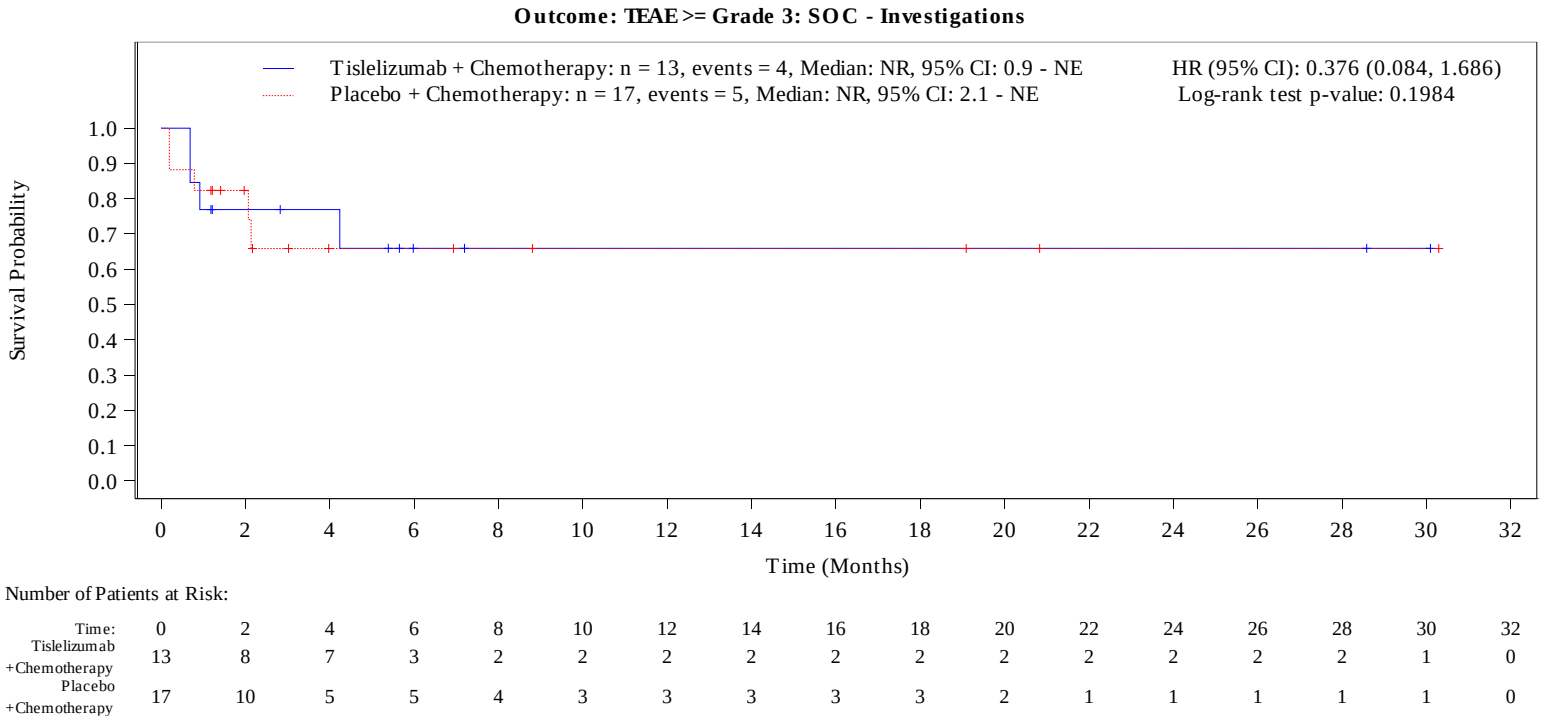
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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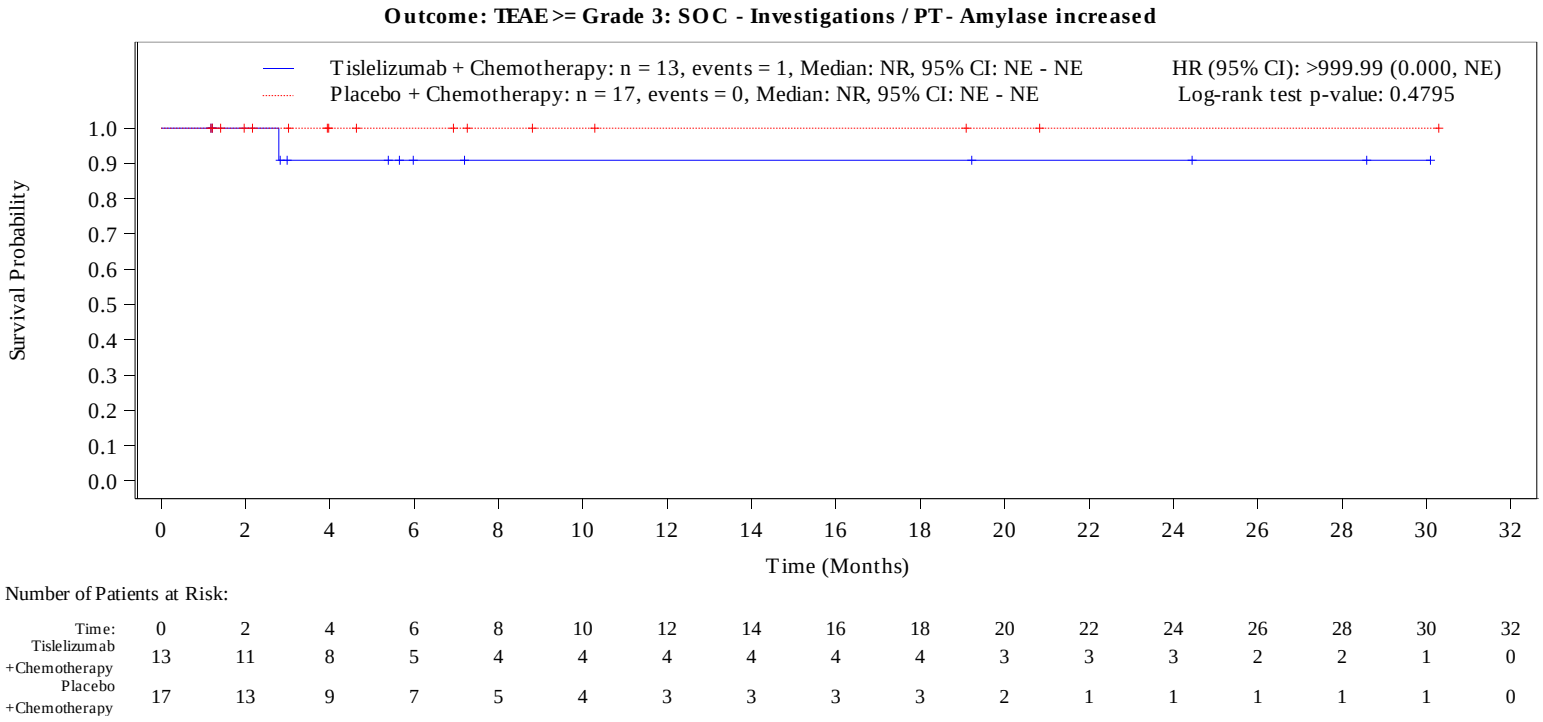
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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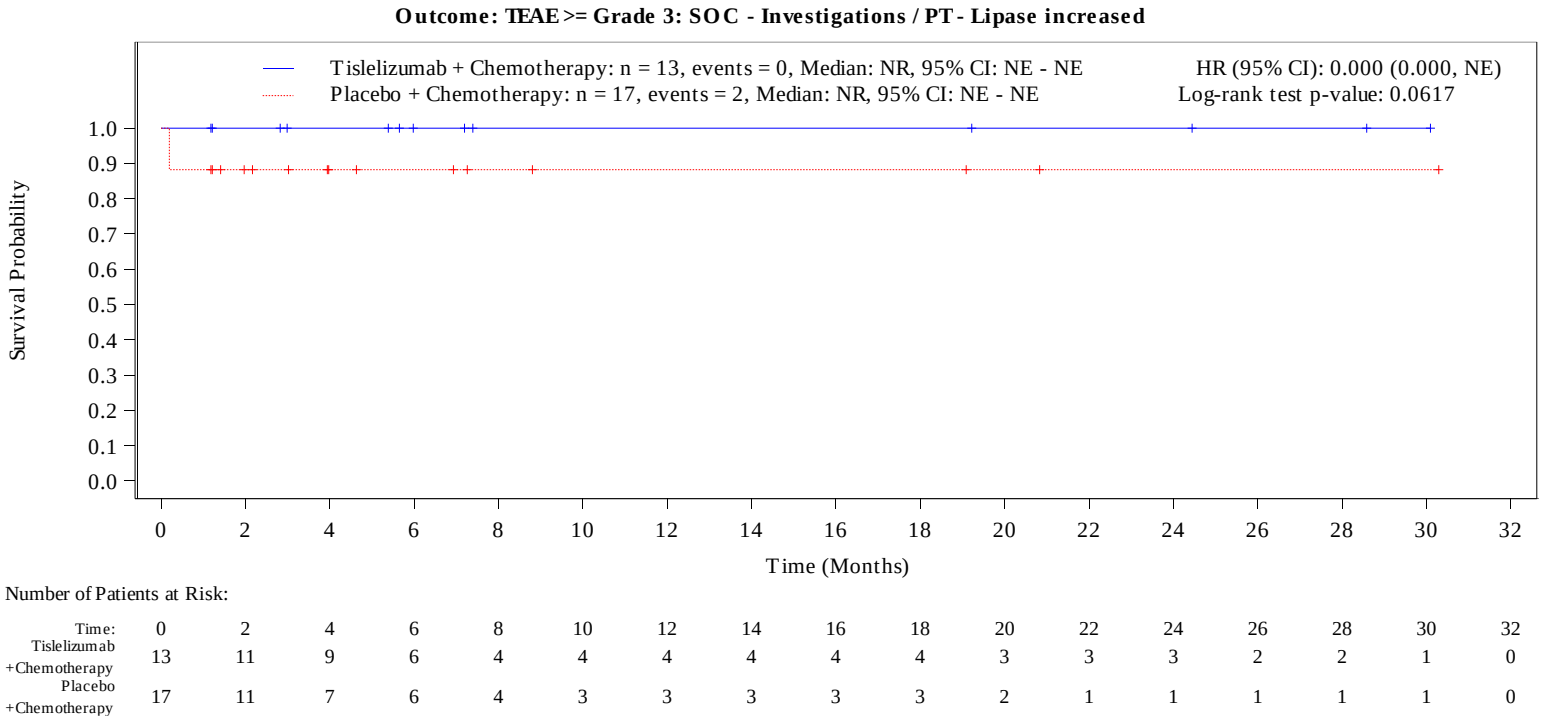
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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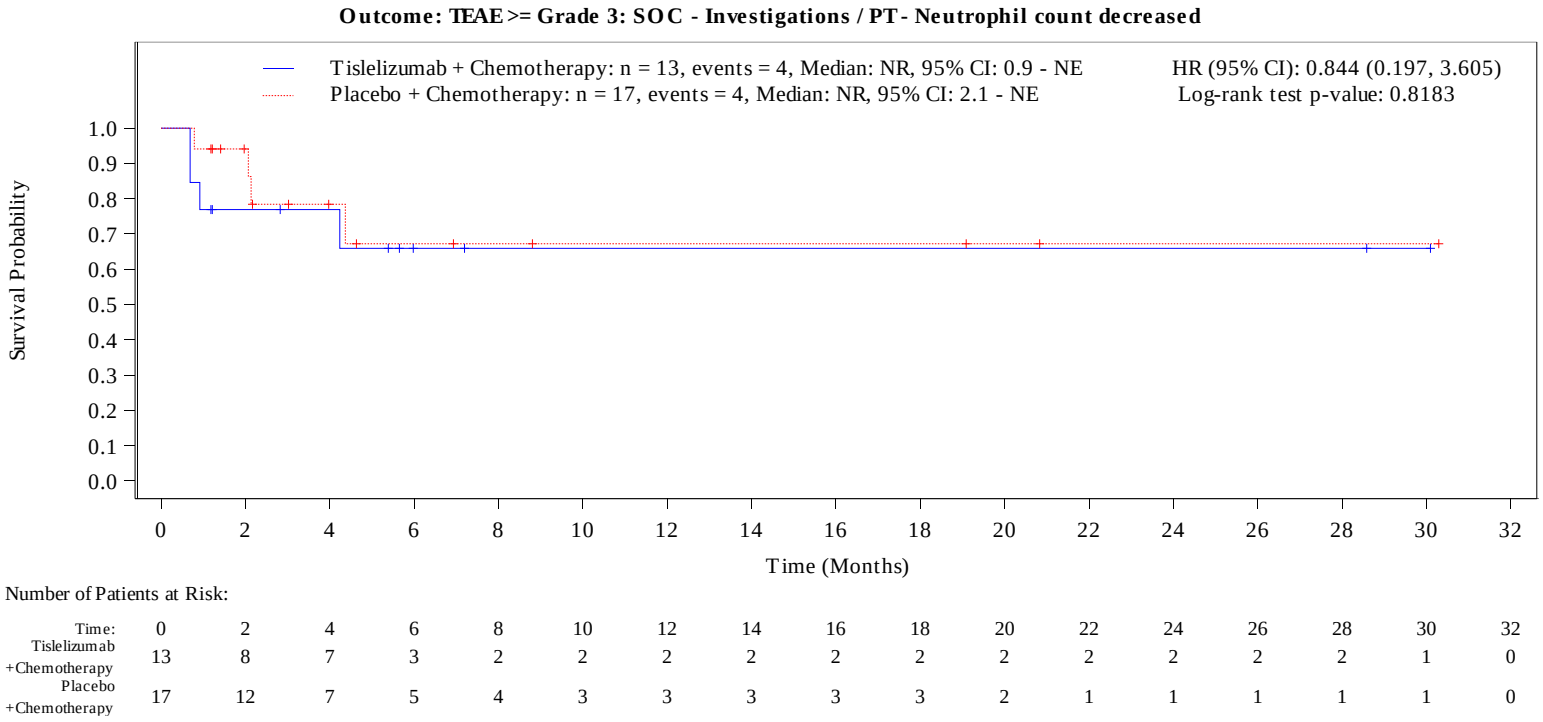
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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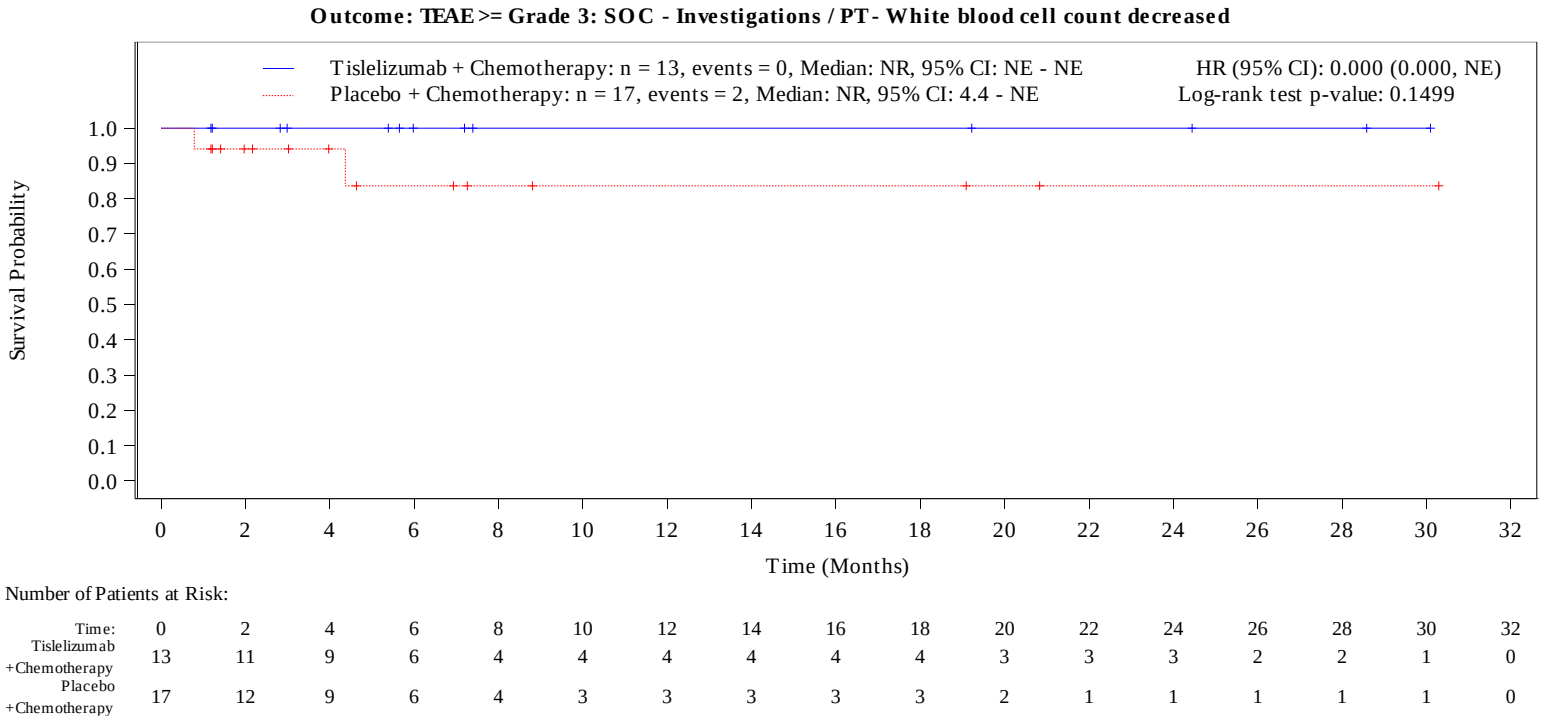
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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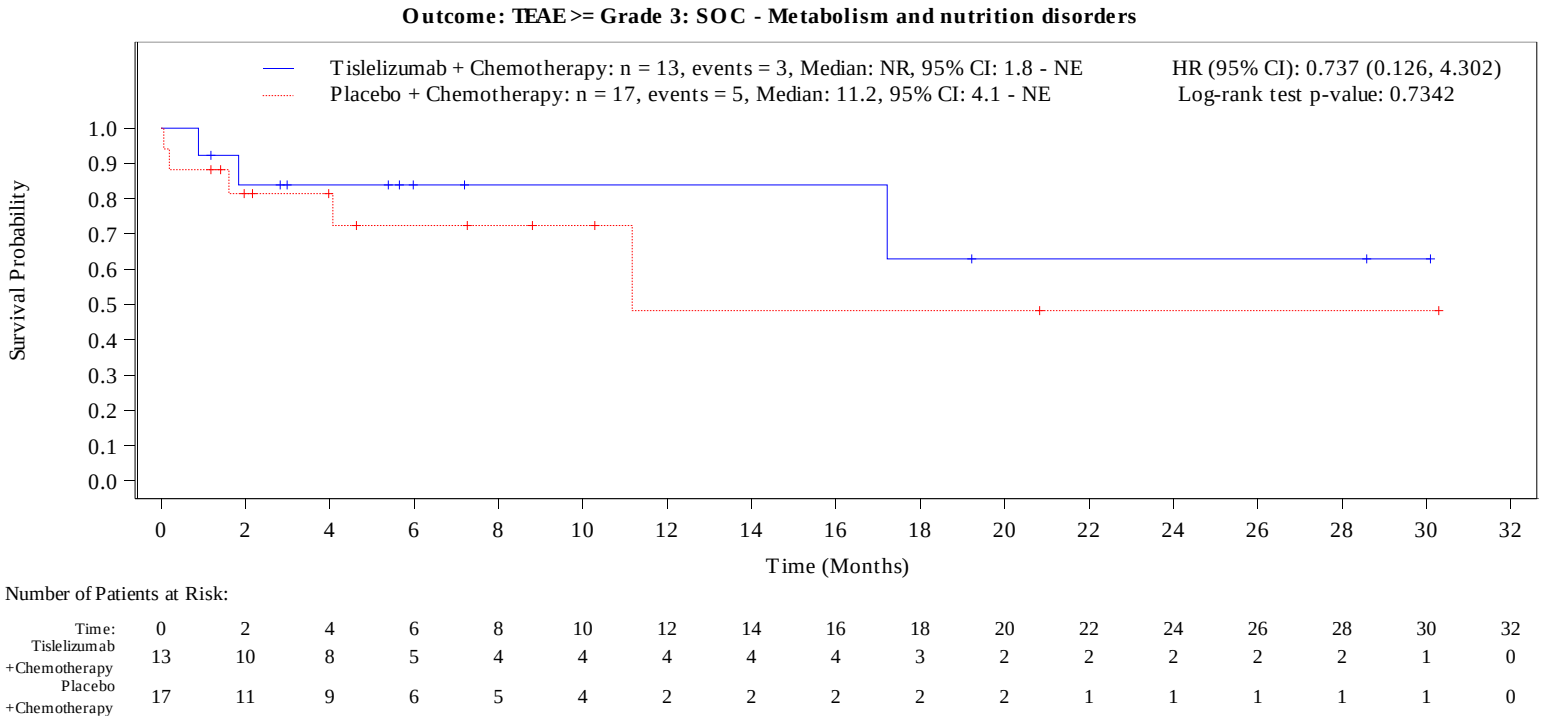
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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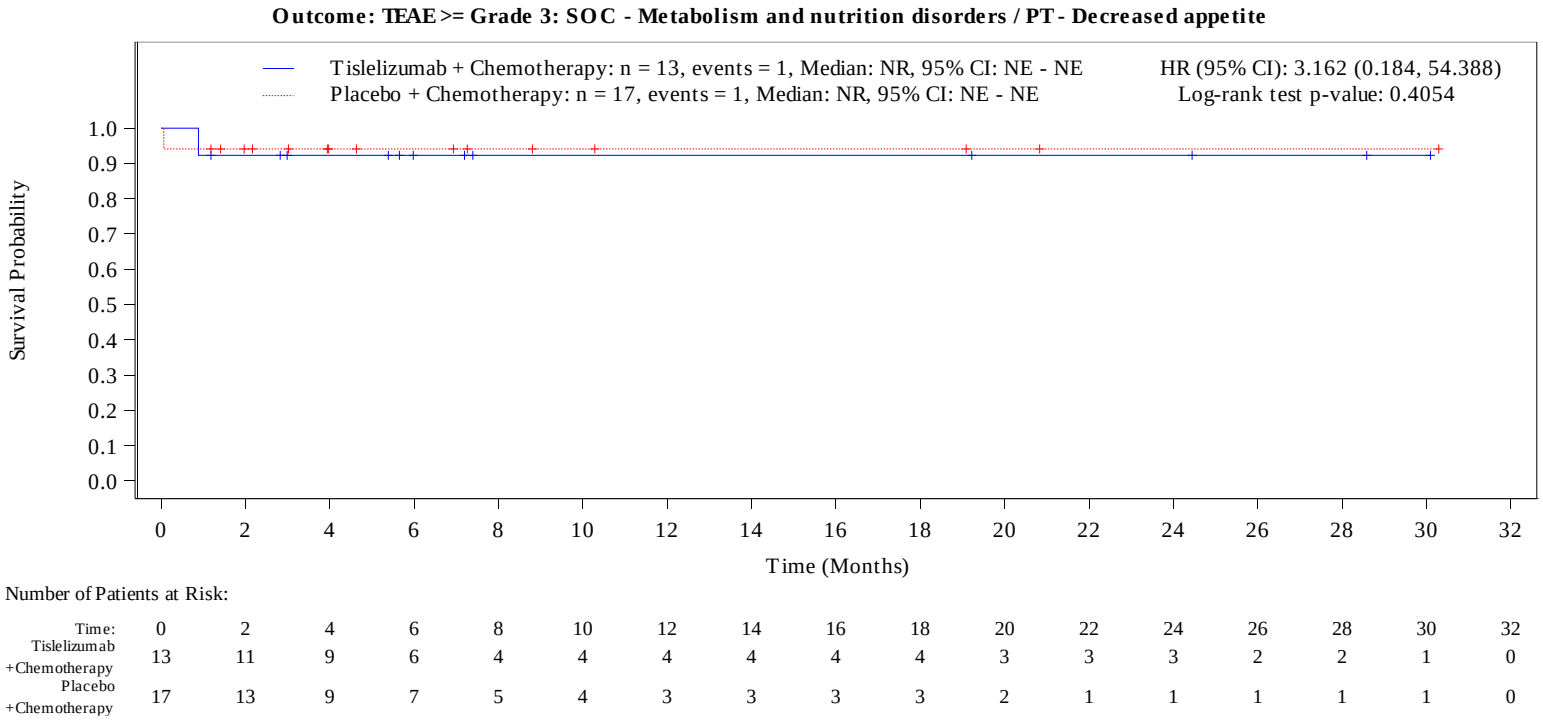
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

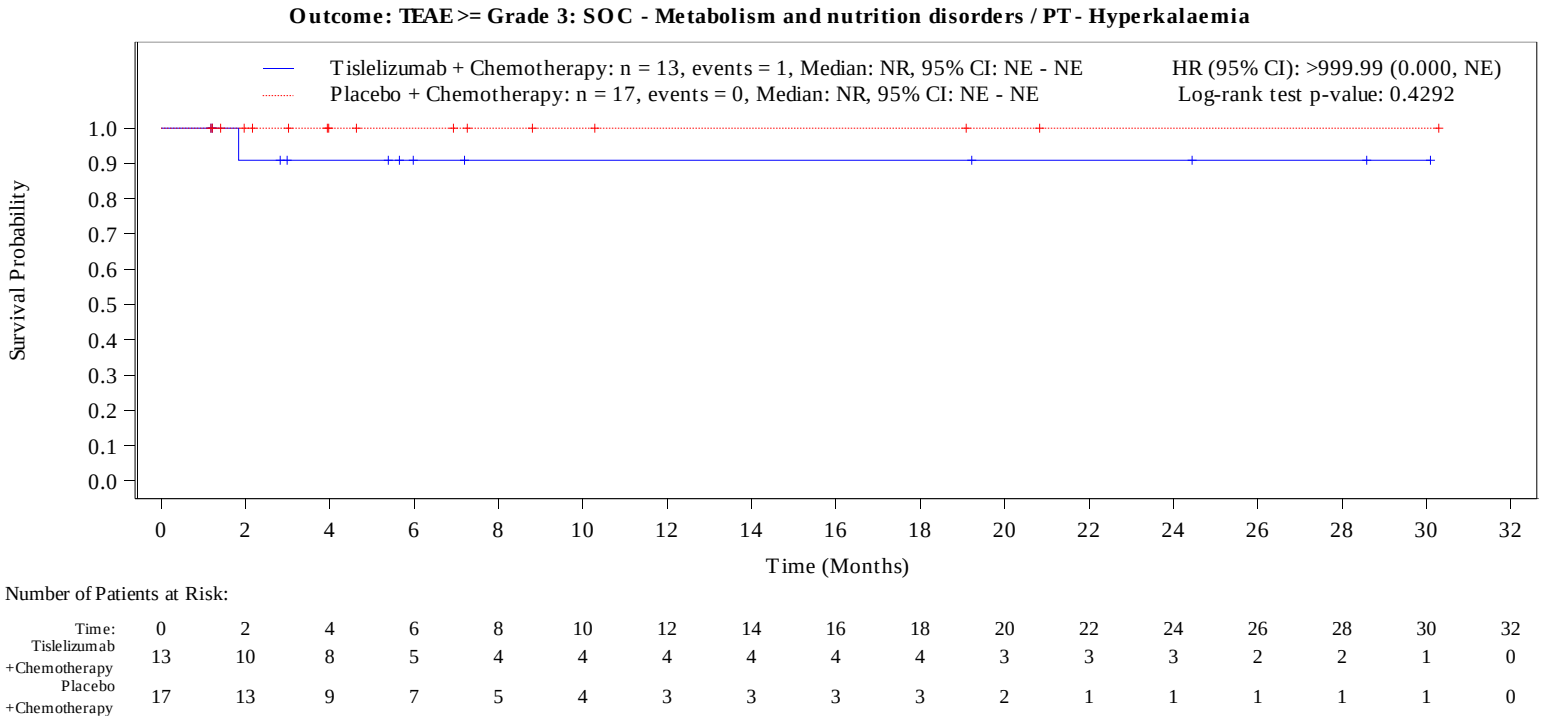

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

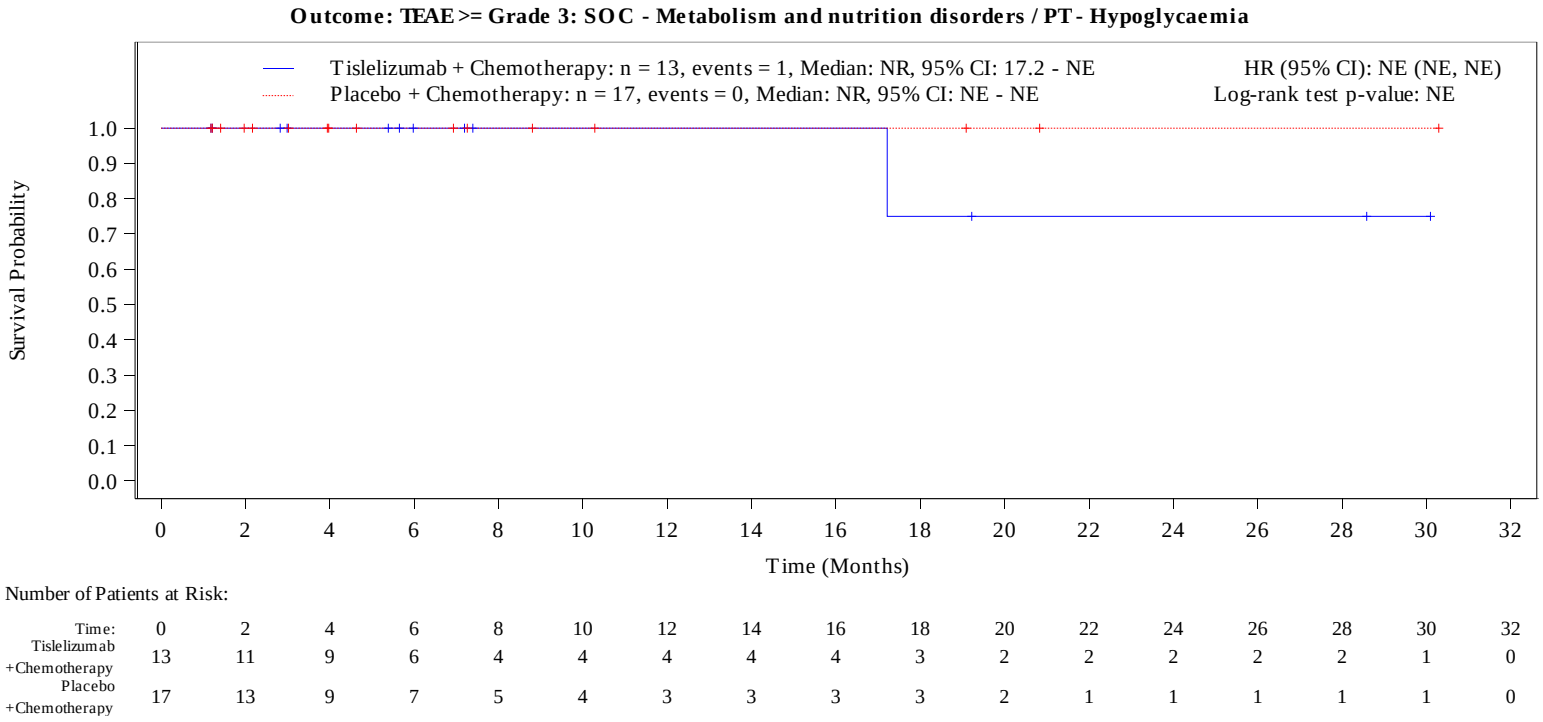

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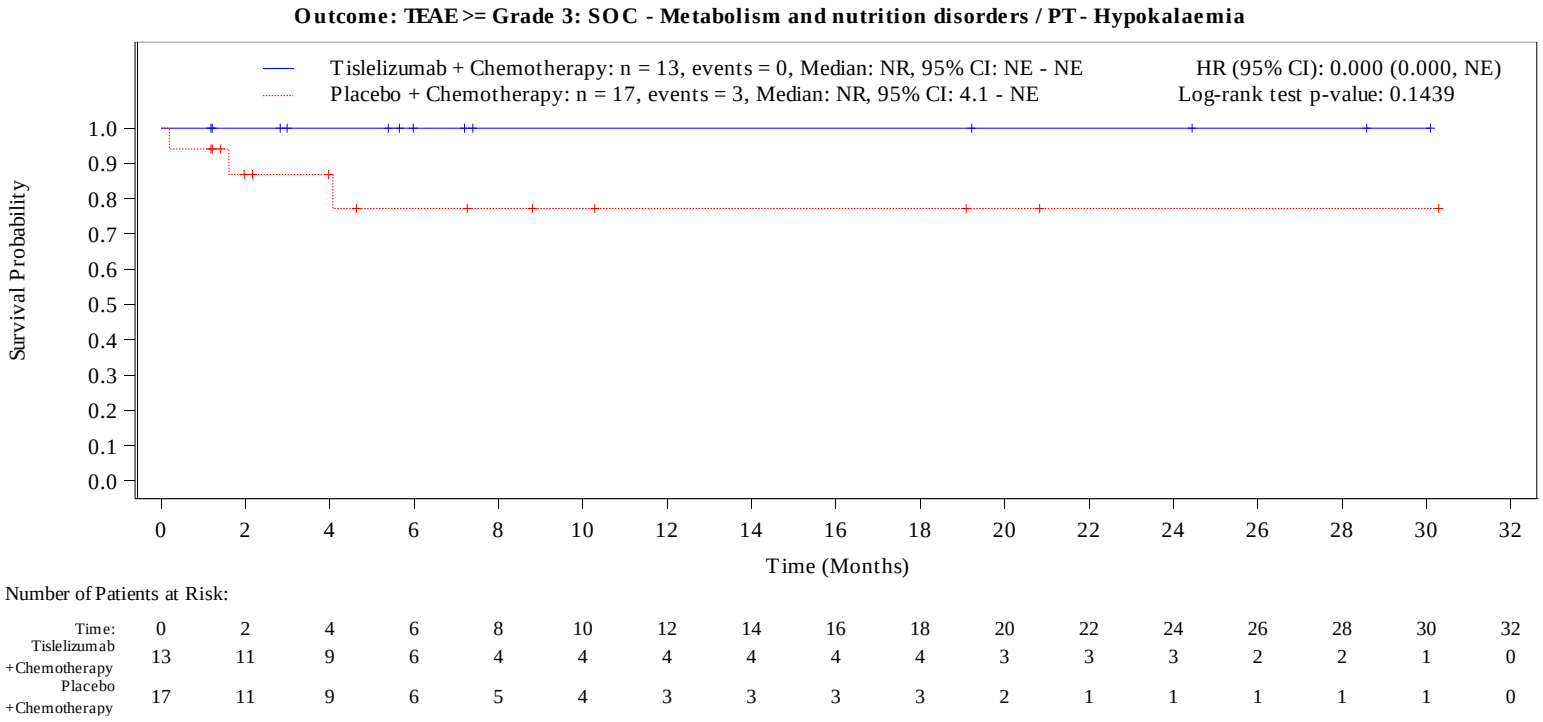
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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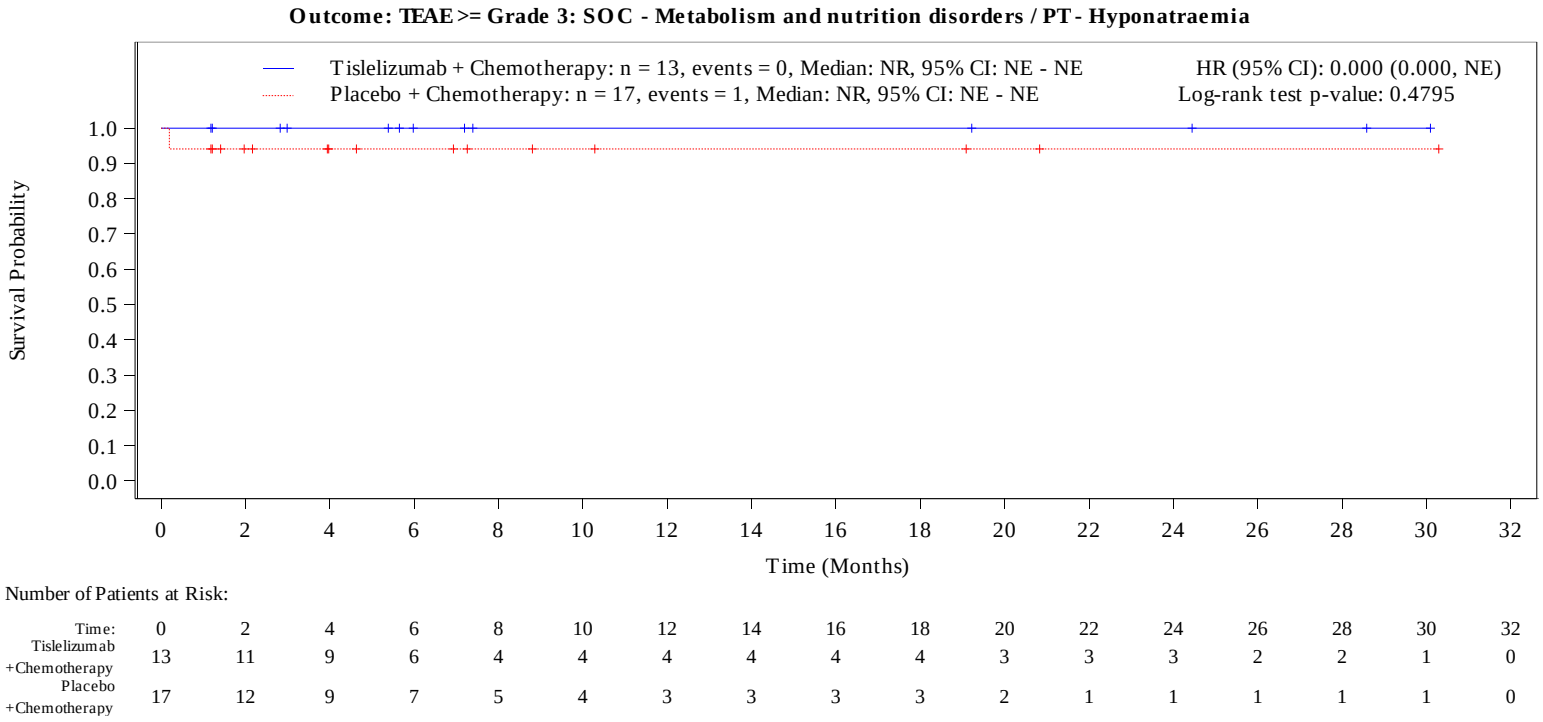
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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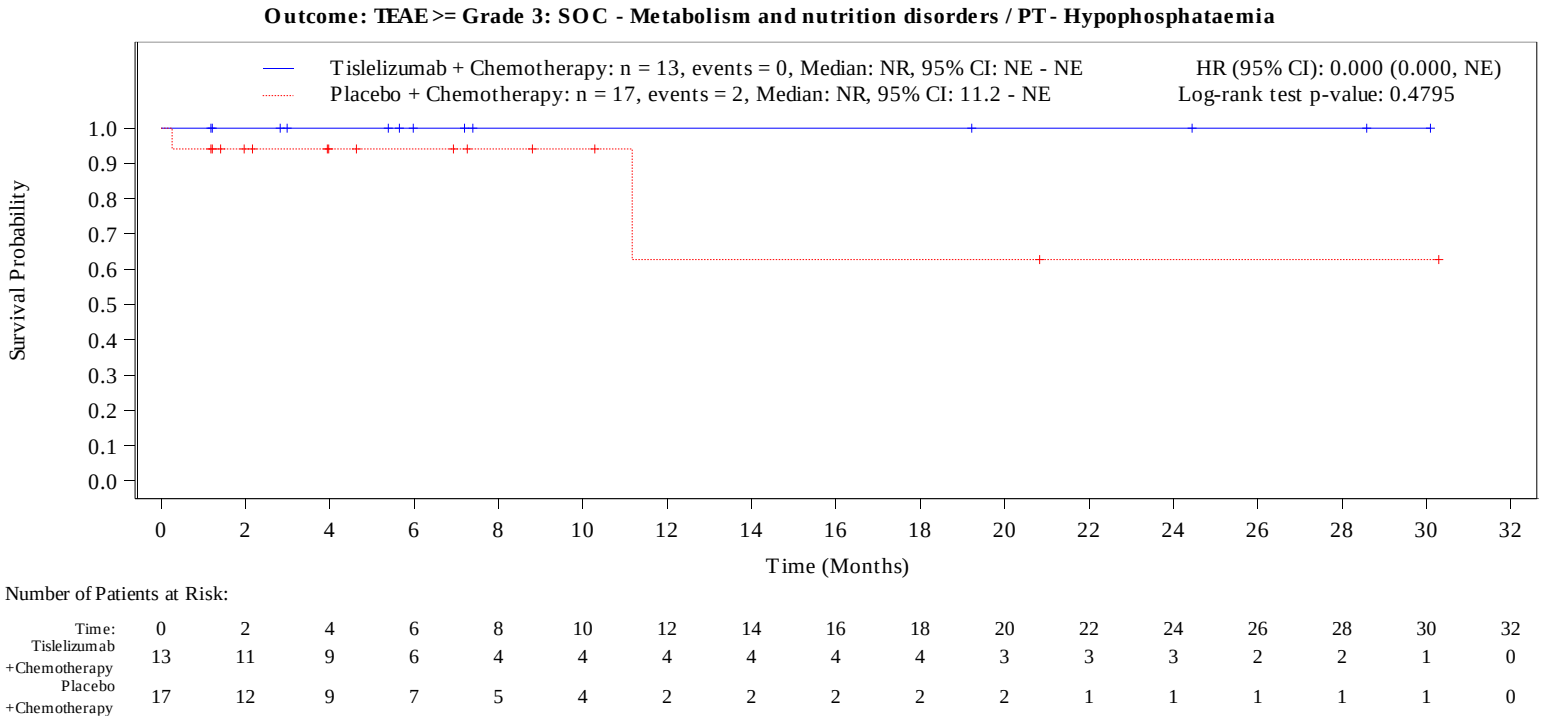
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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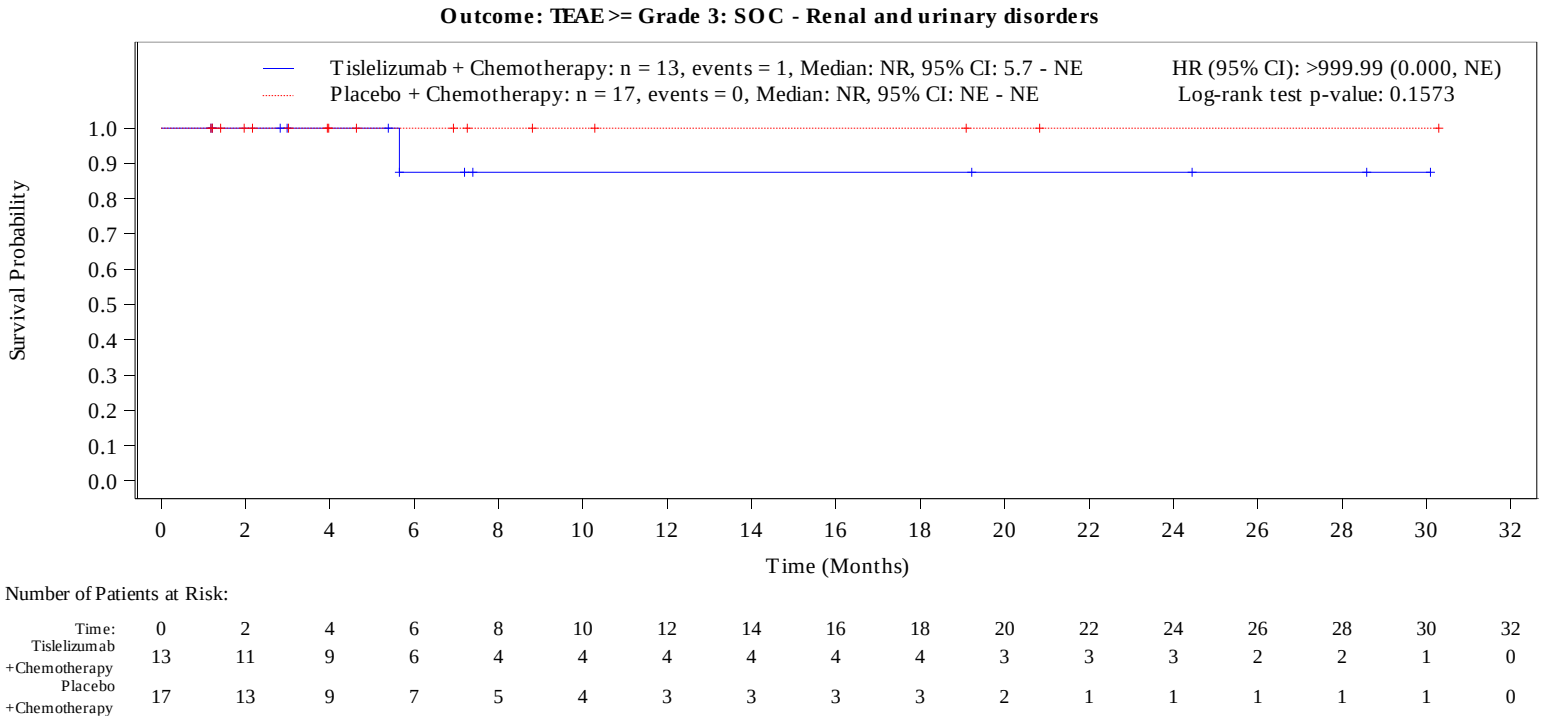
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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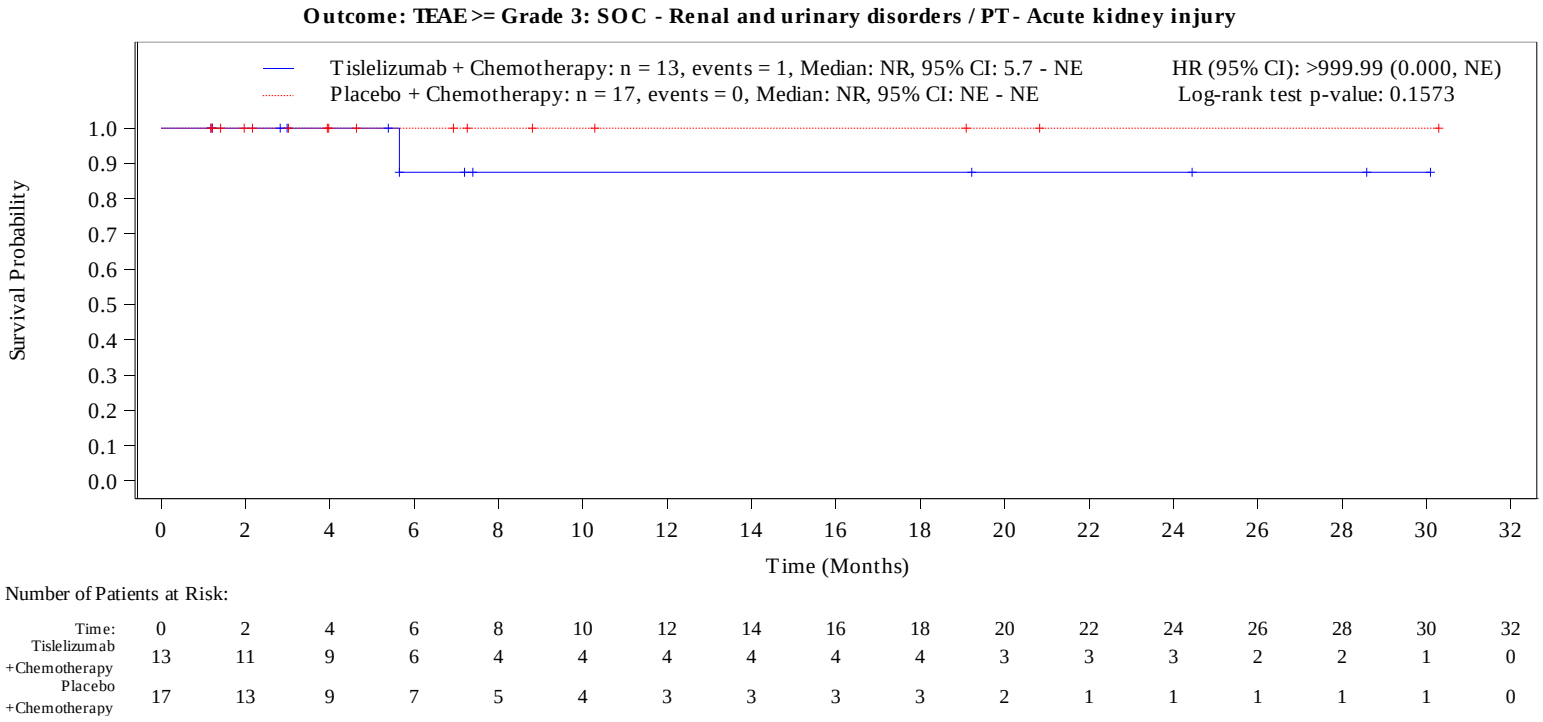
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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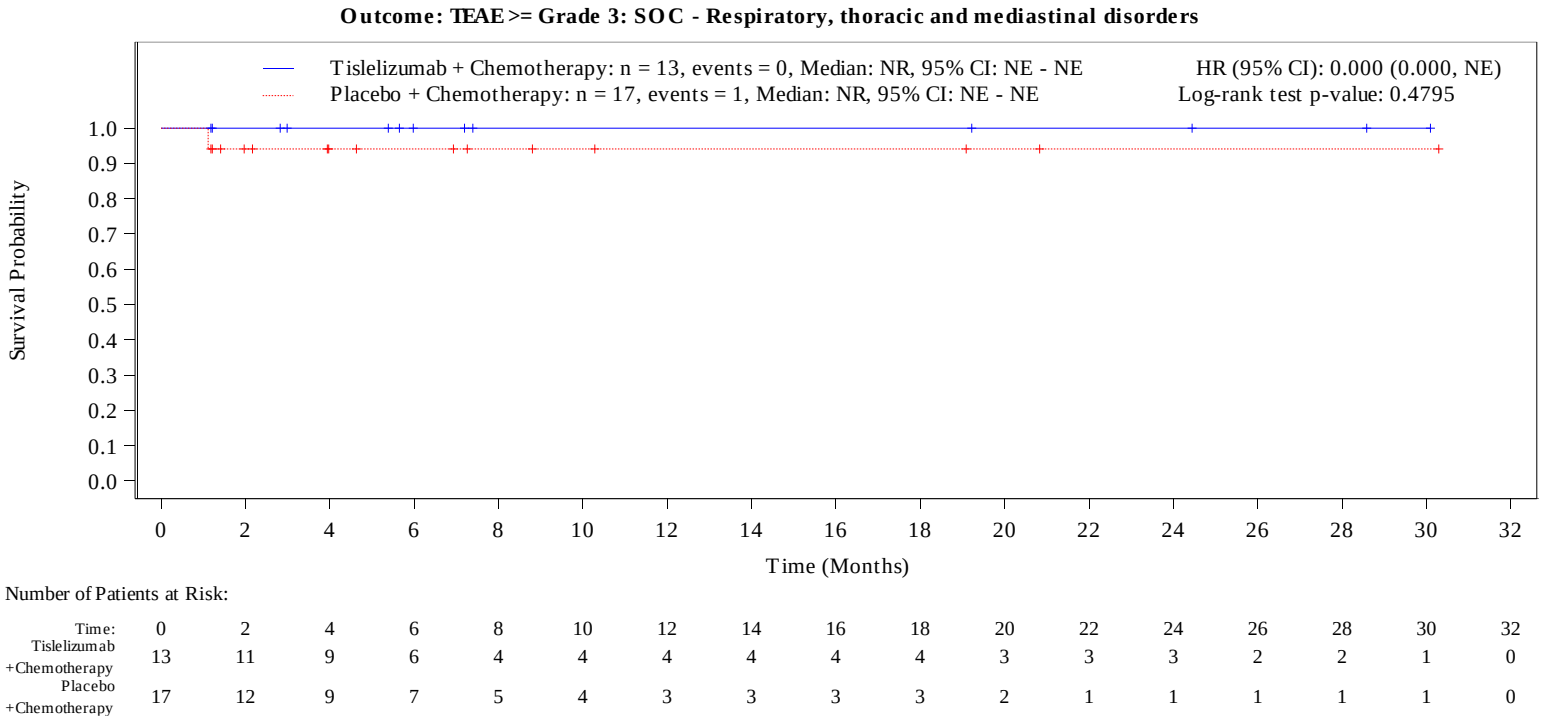
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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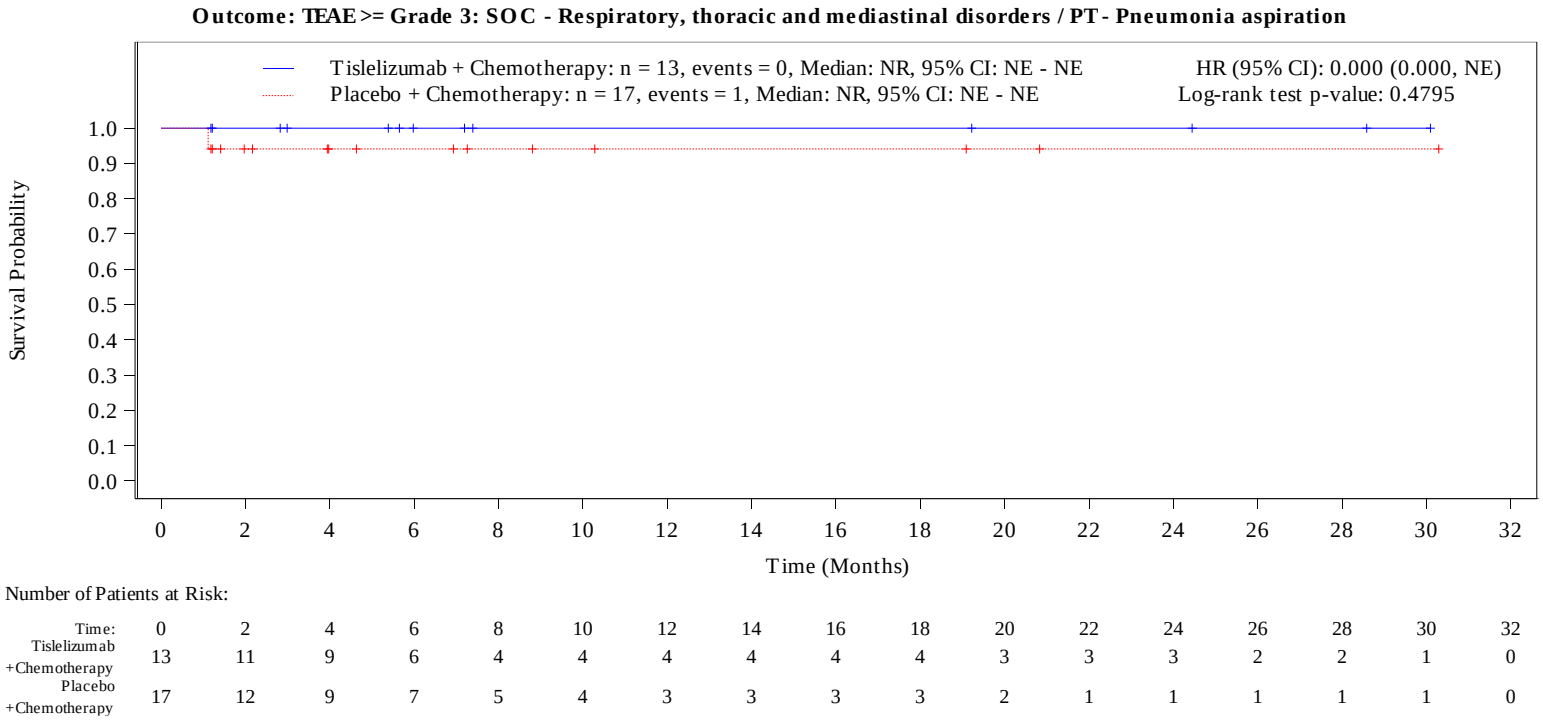
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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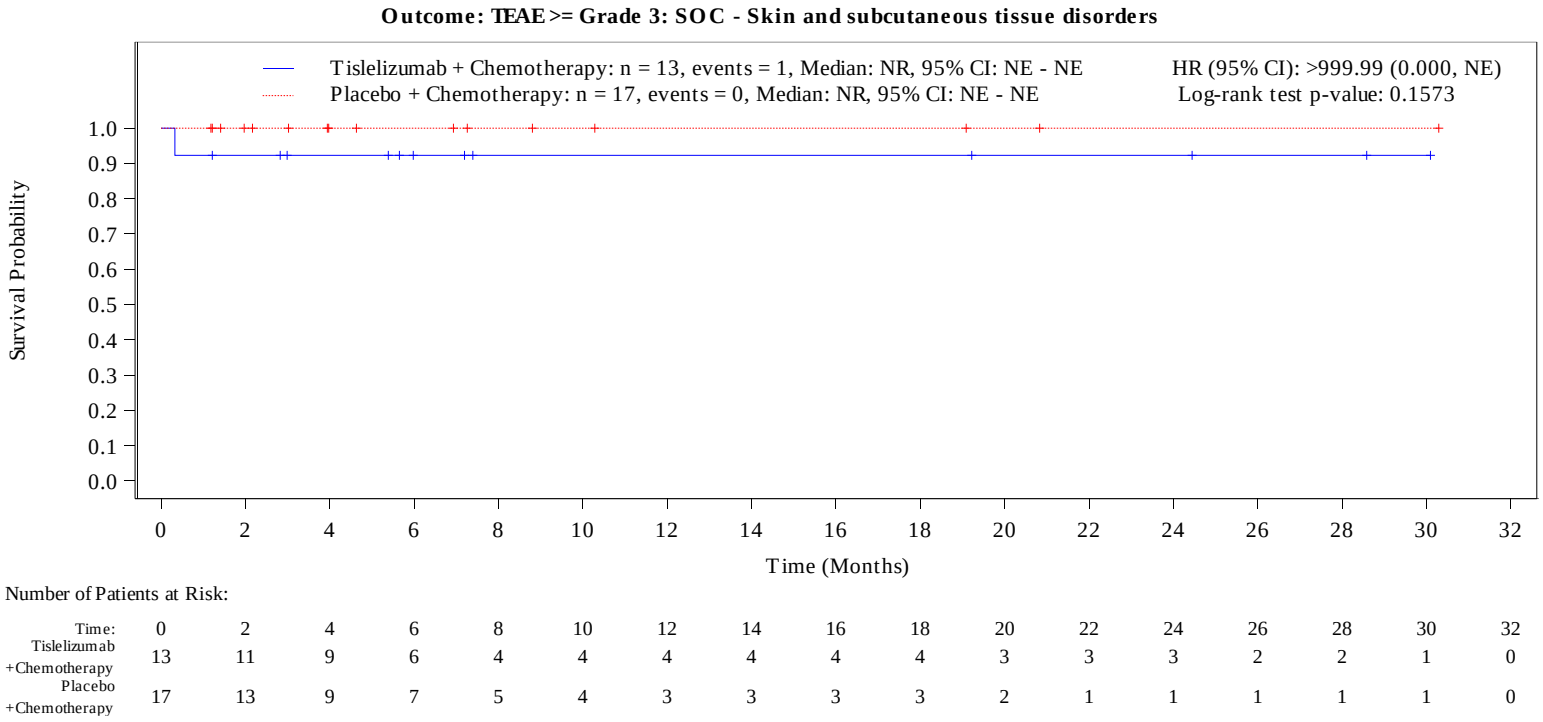
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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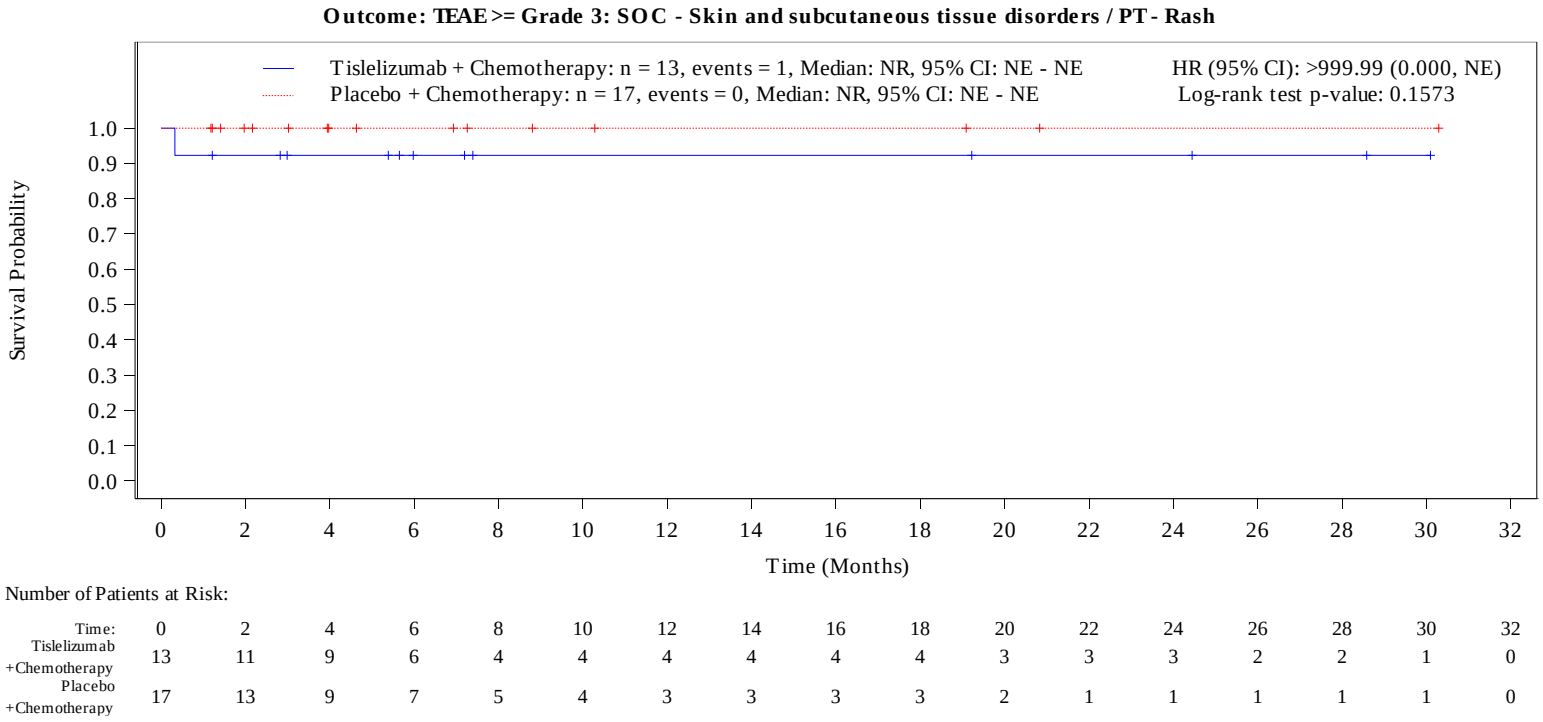
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-3-km-aesocpt-gr3-pop1-ia.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

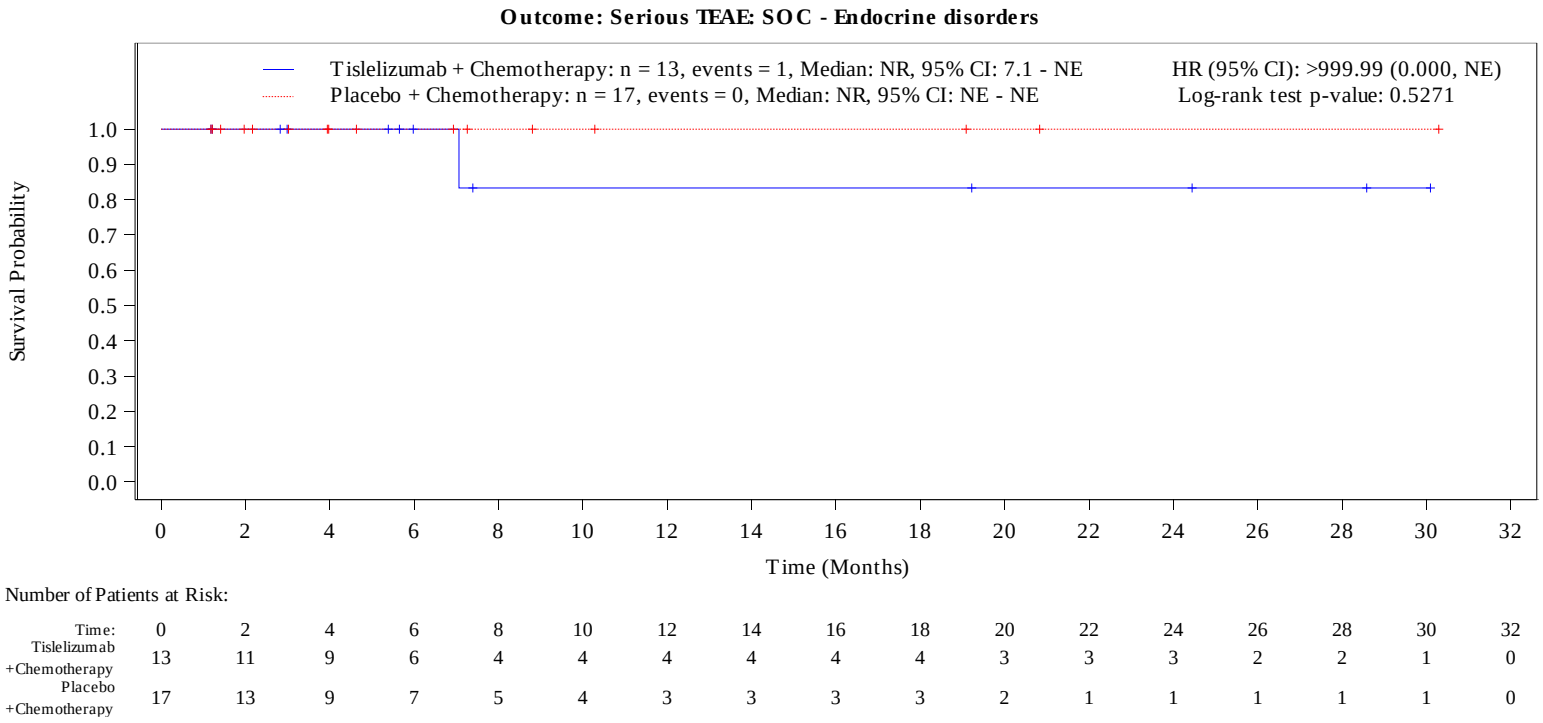

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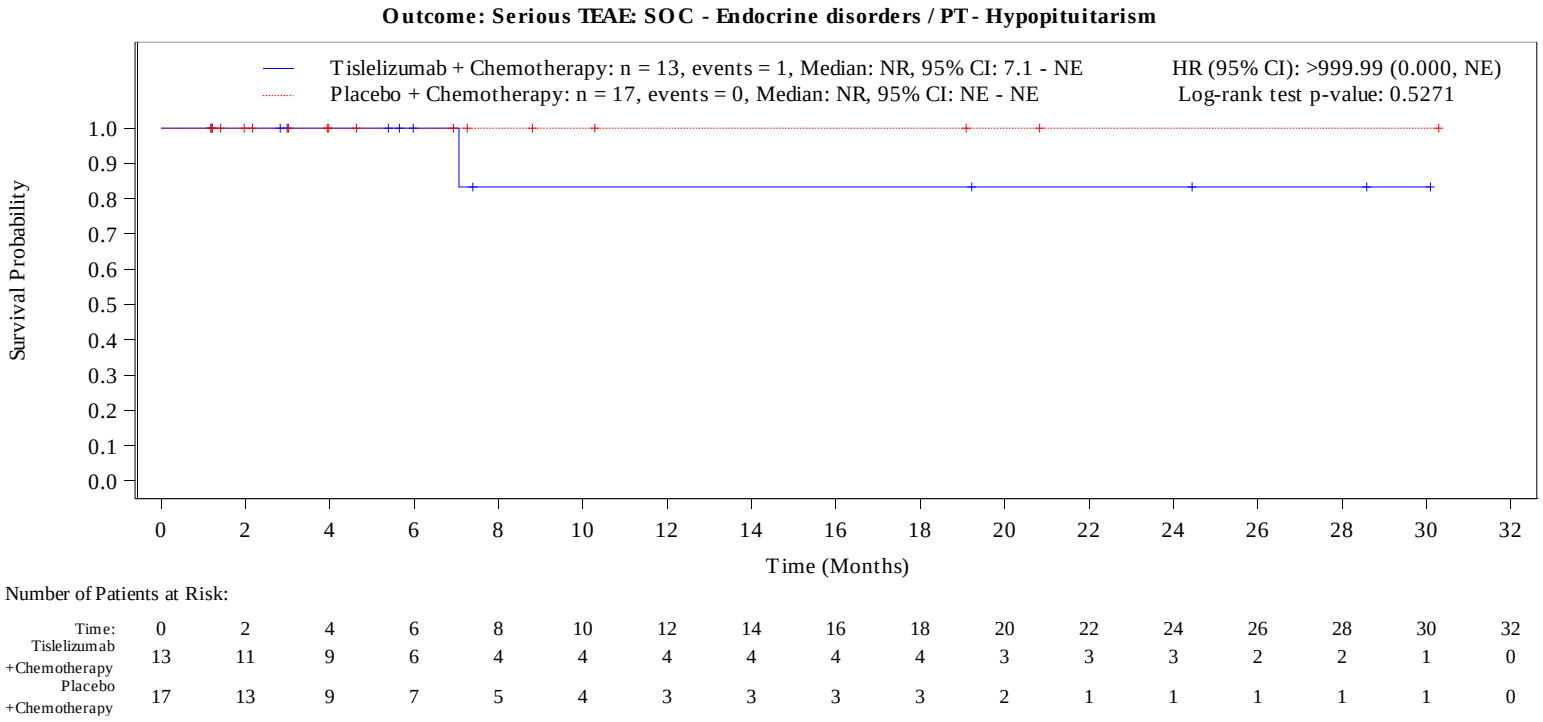
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
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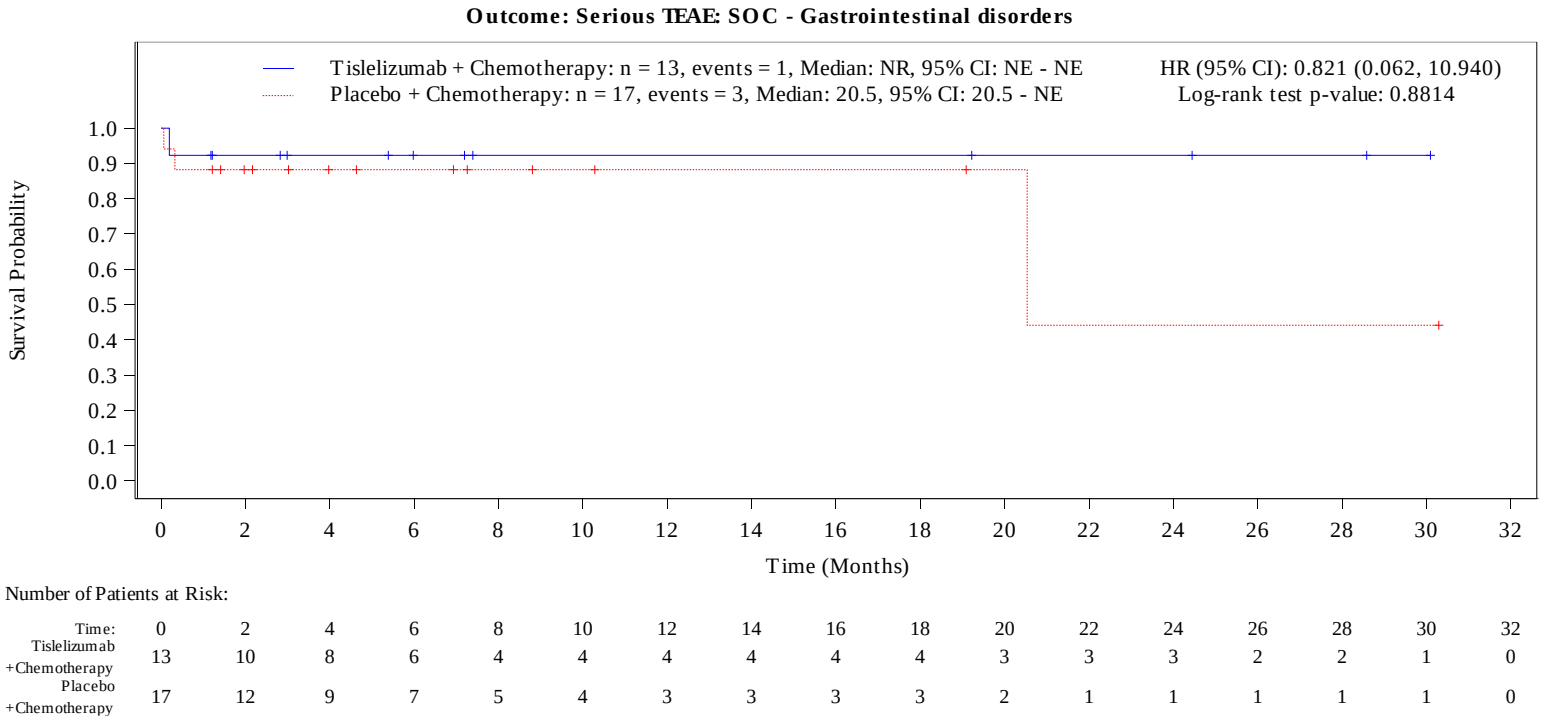

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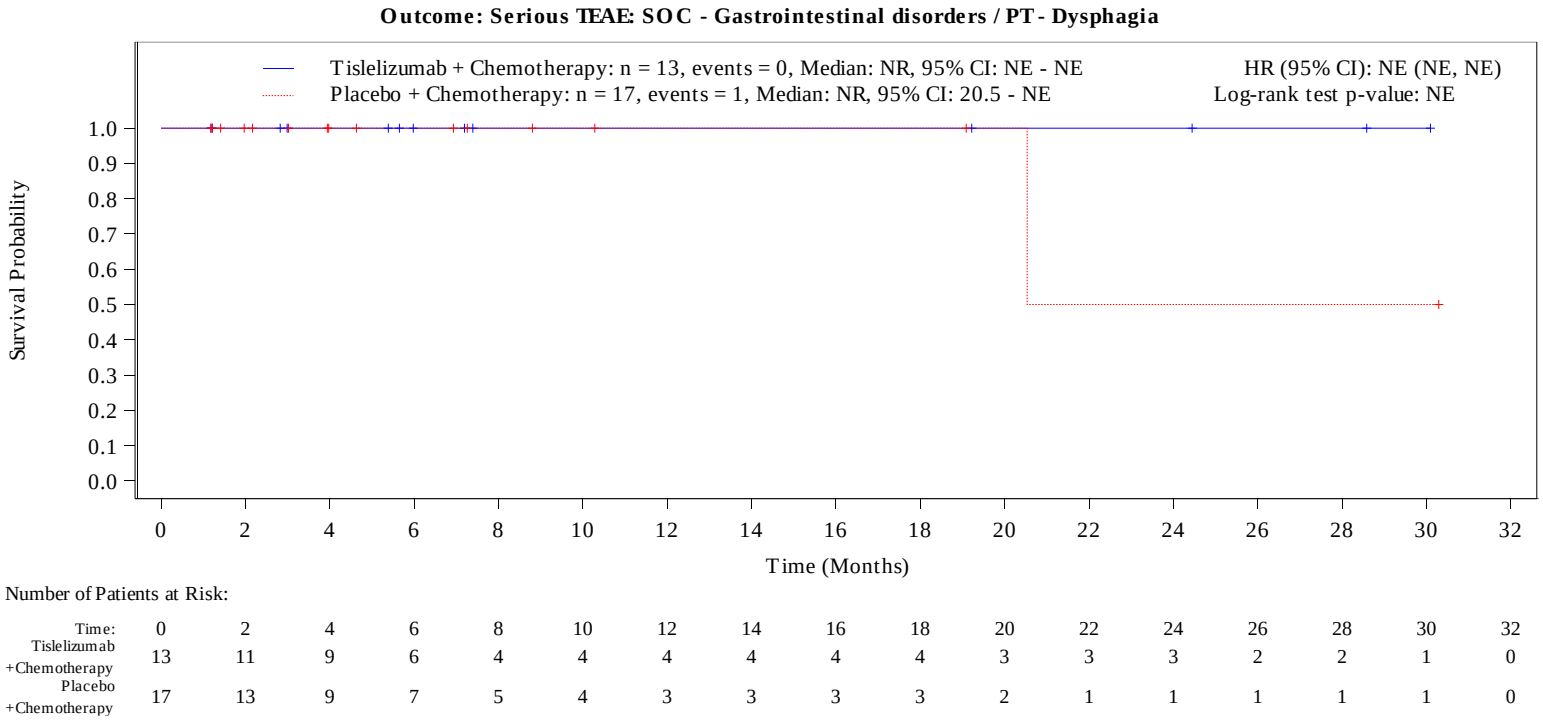

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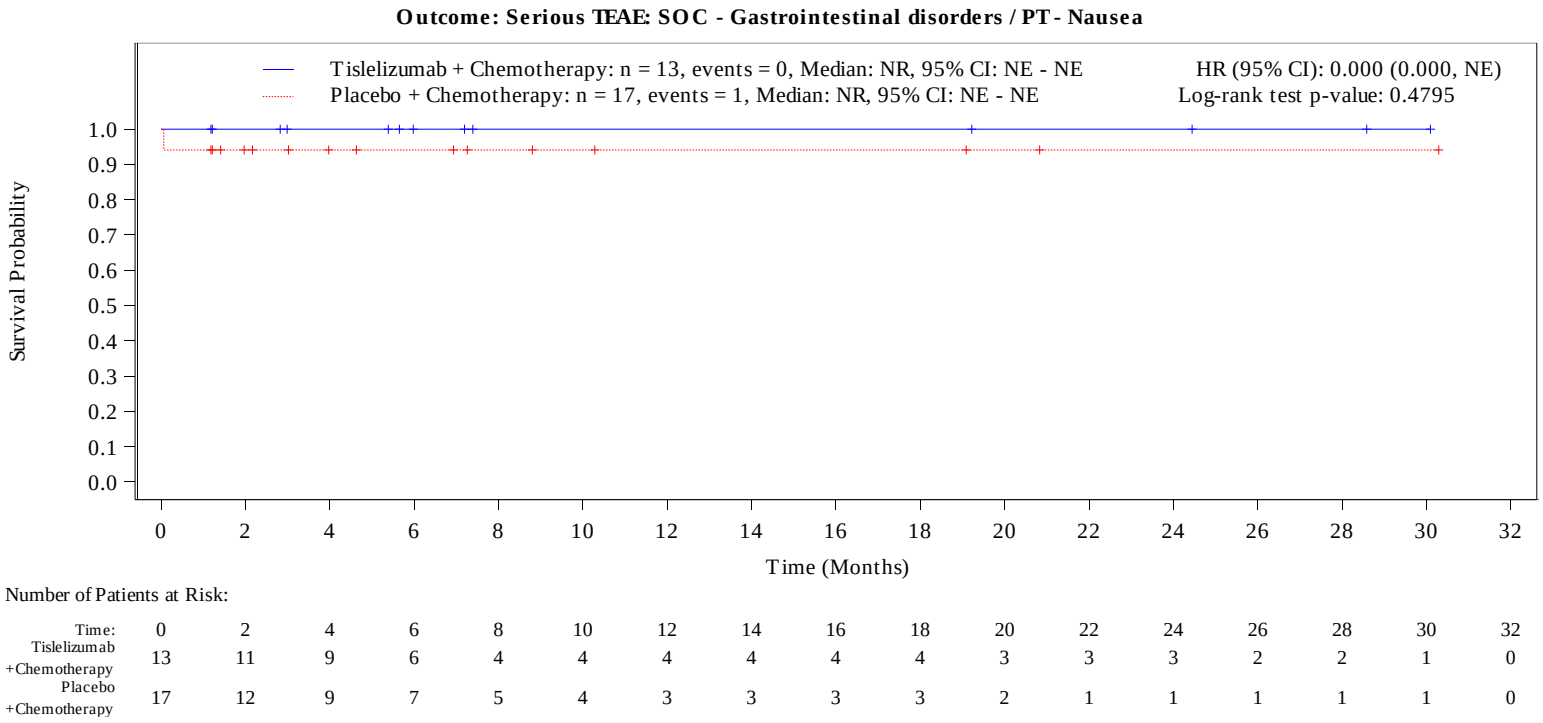

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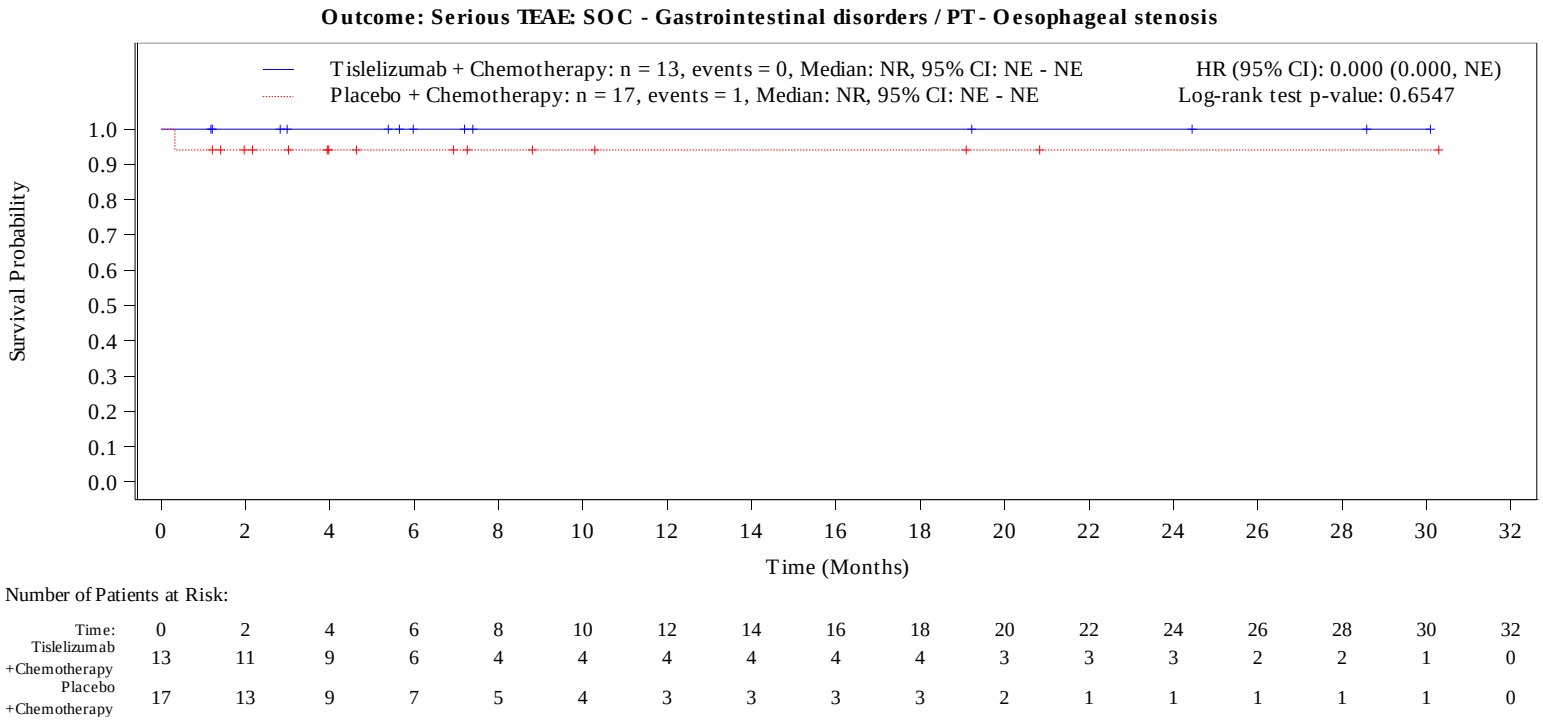

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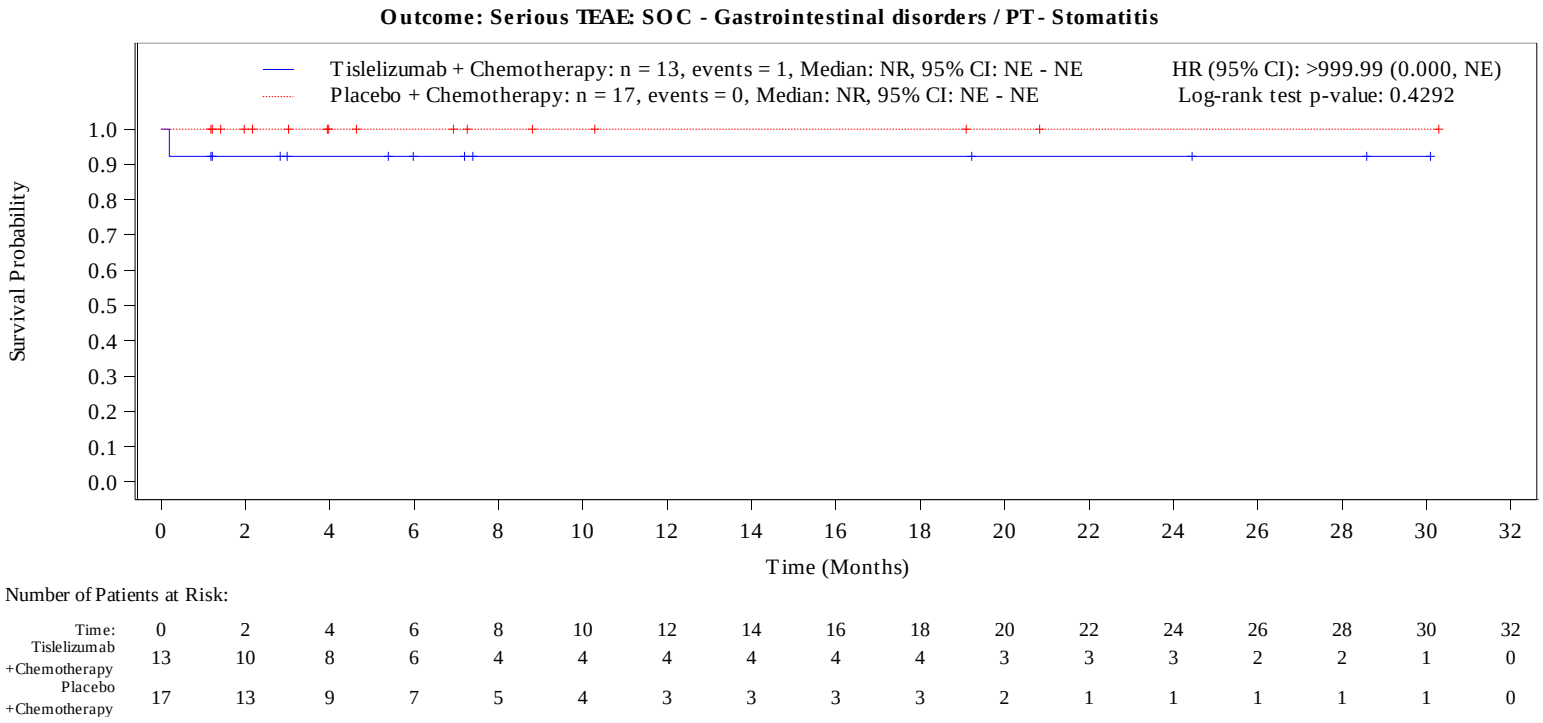

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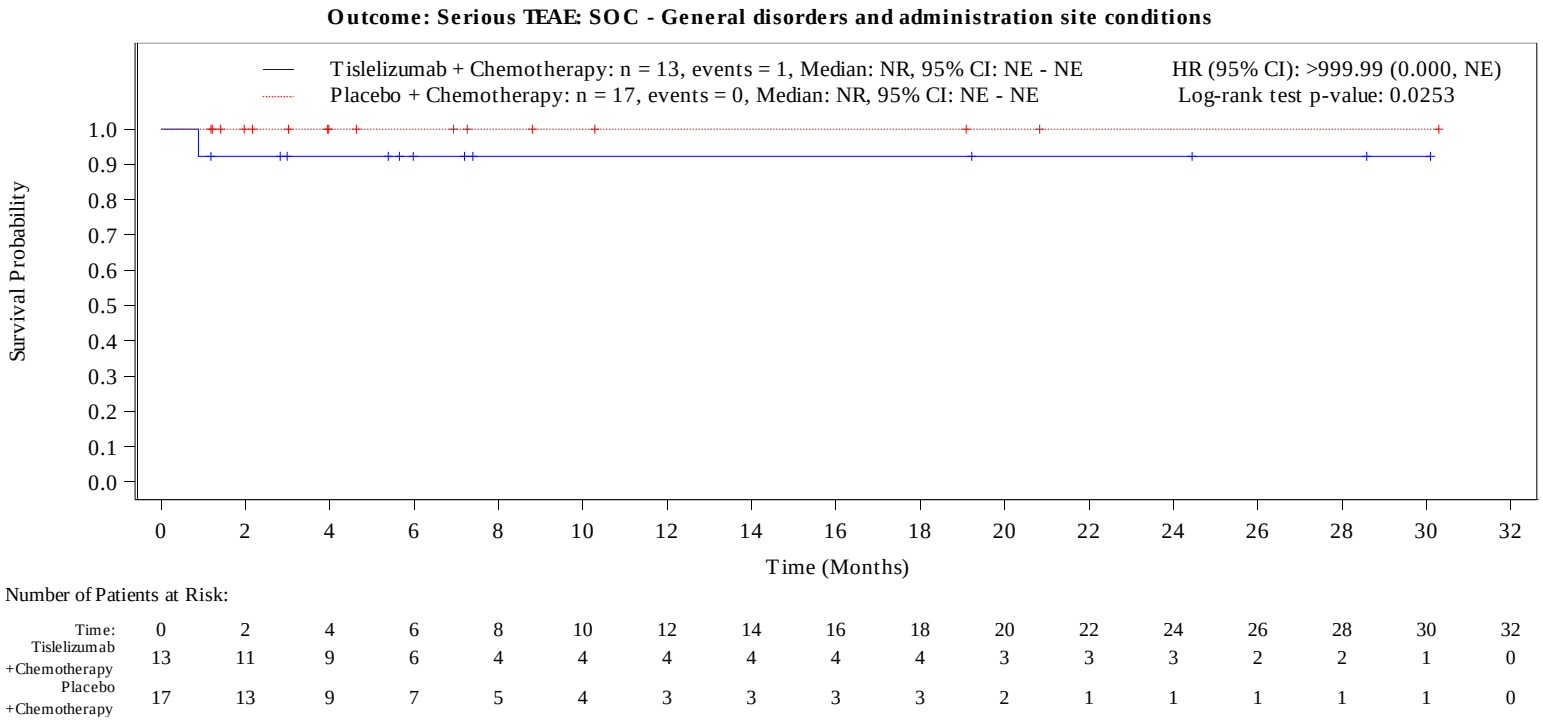

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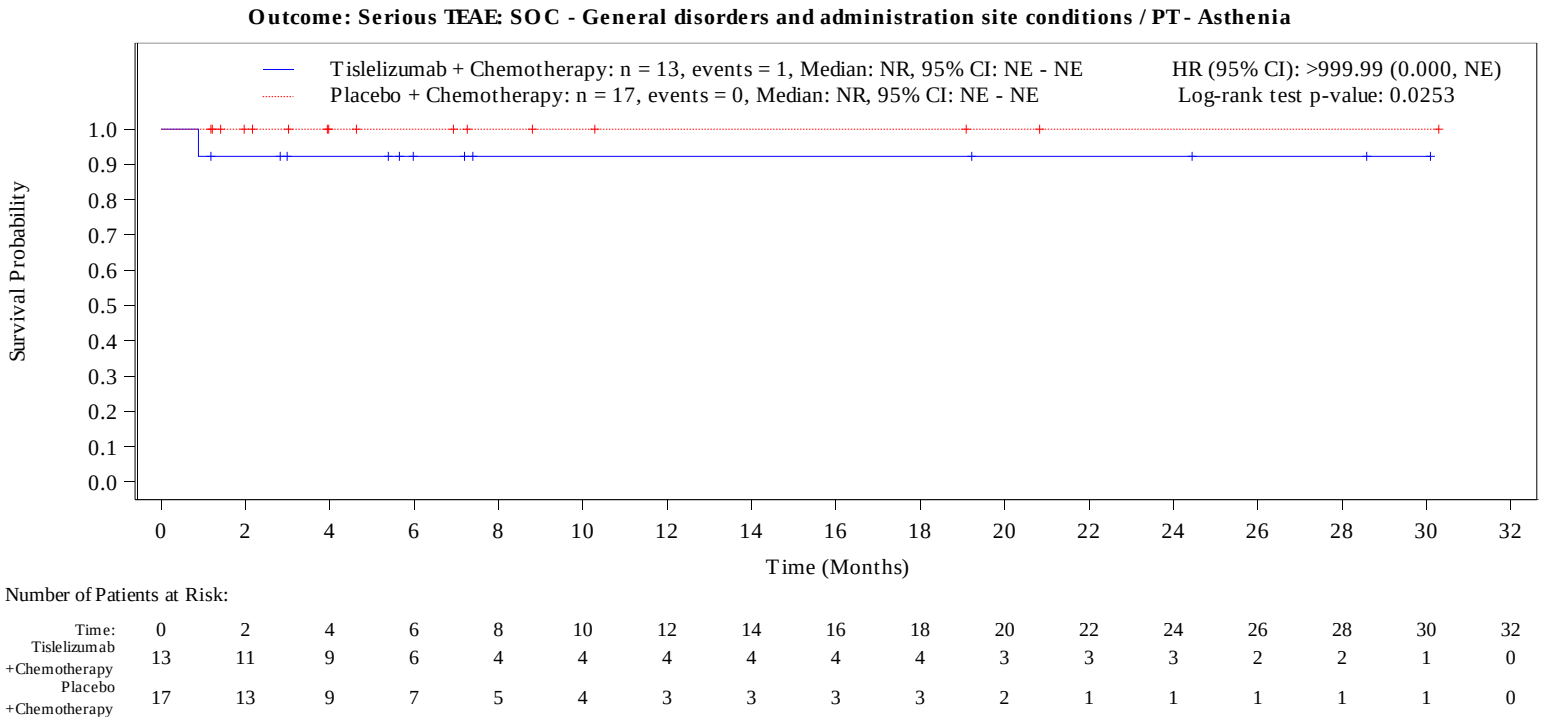

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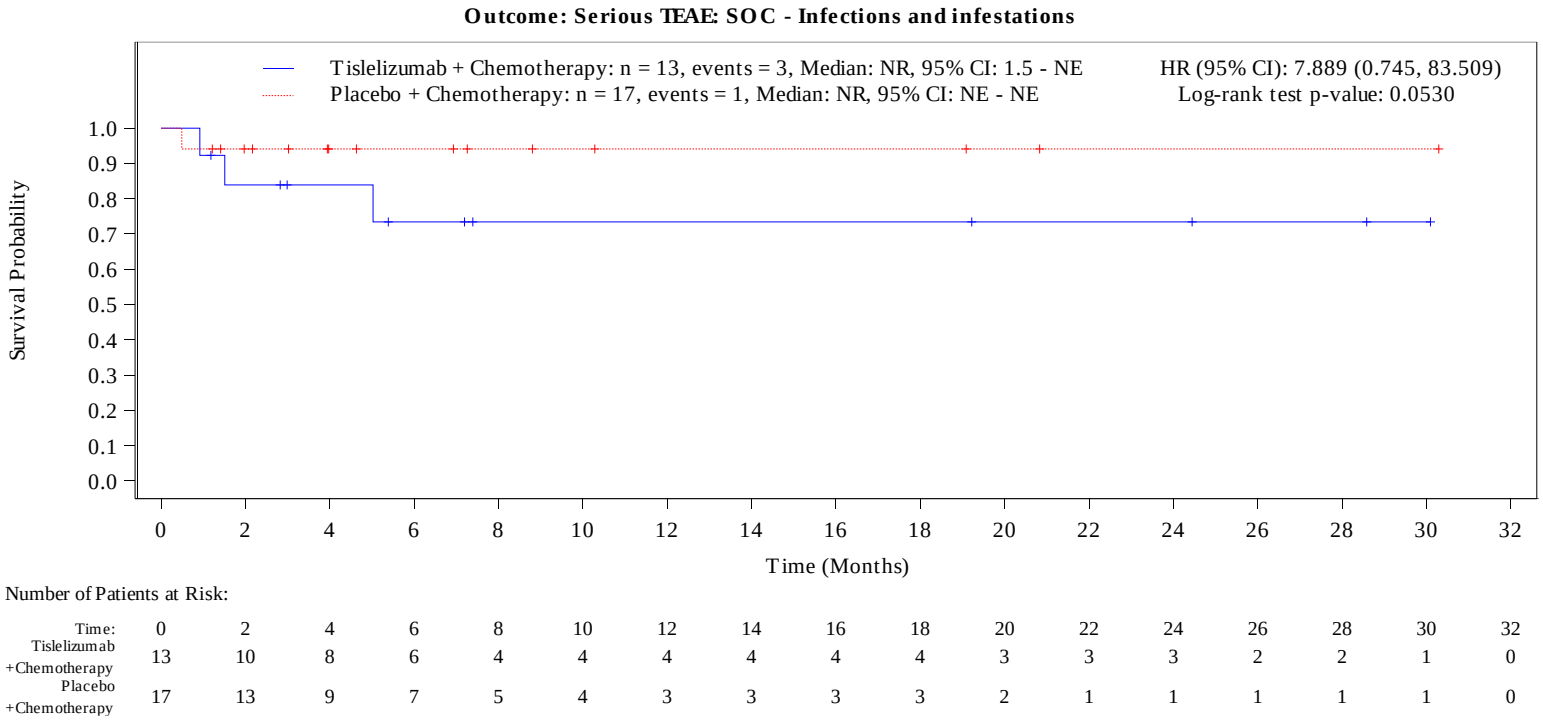

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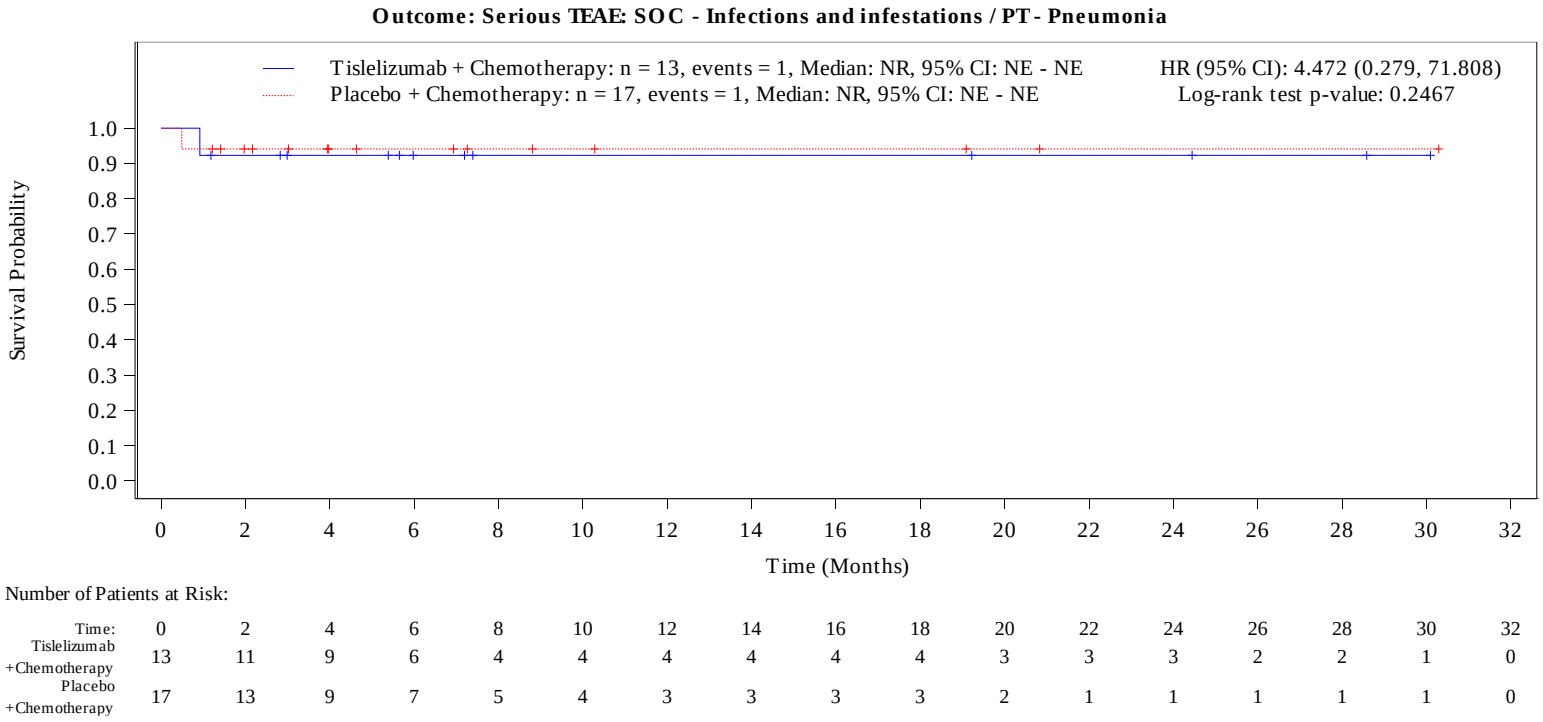

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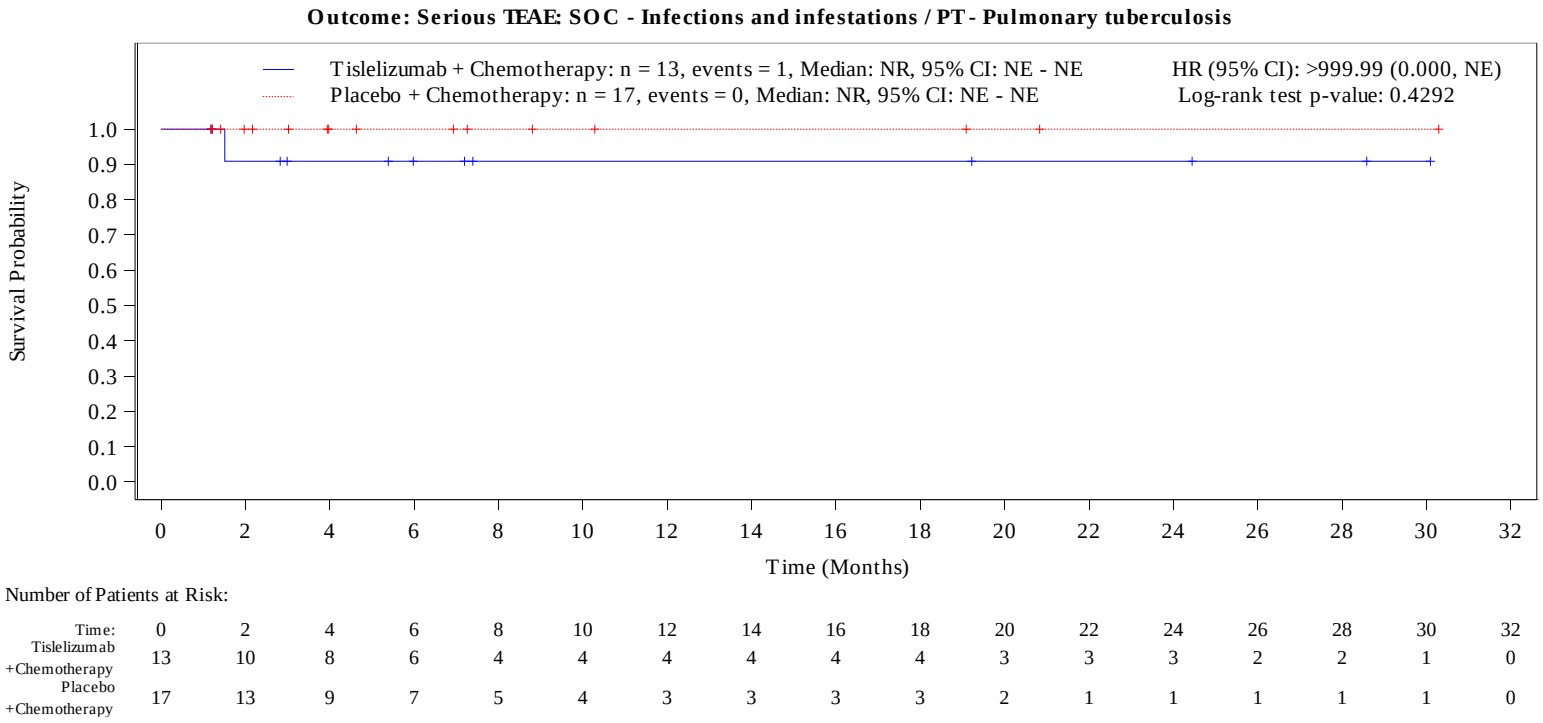

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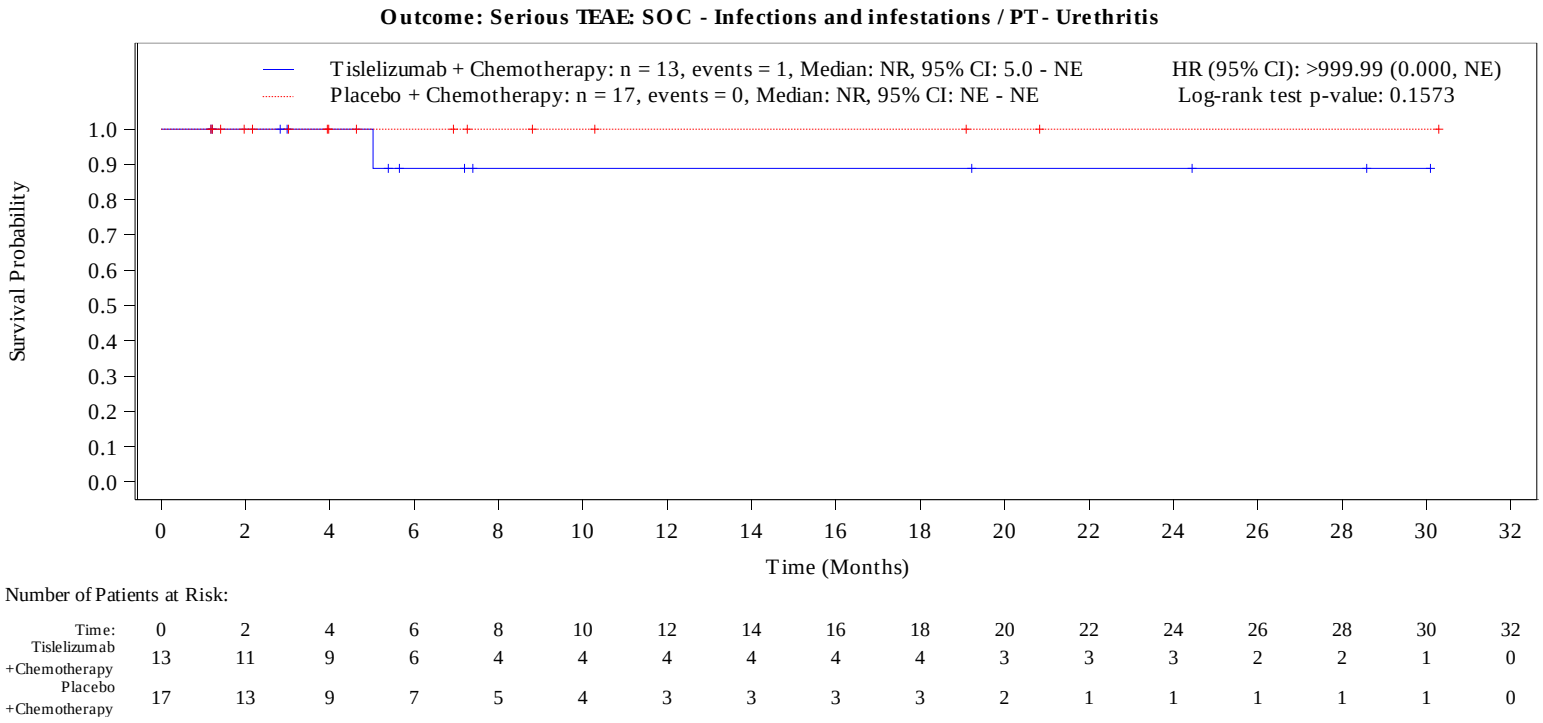

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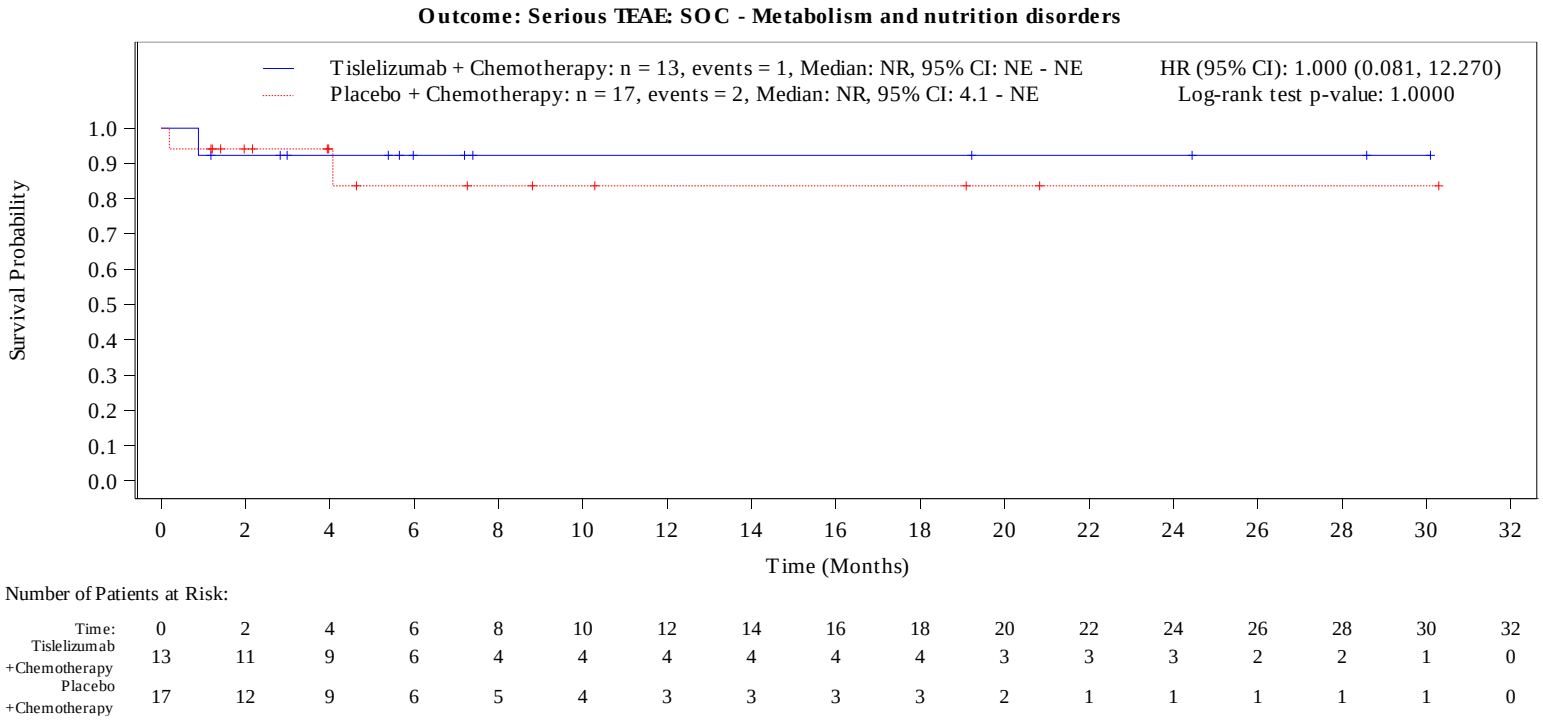

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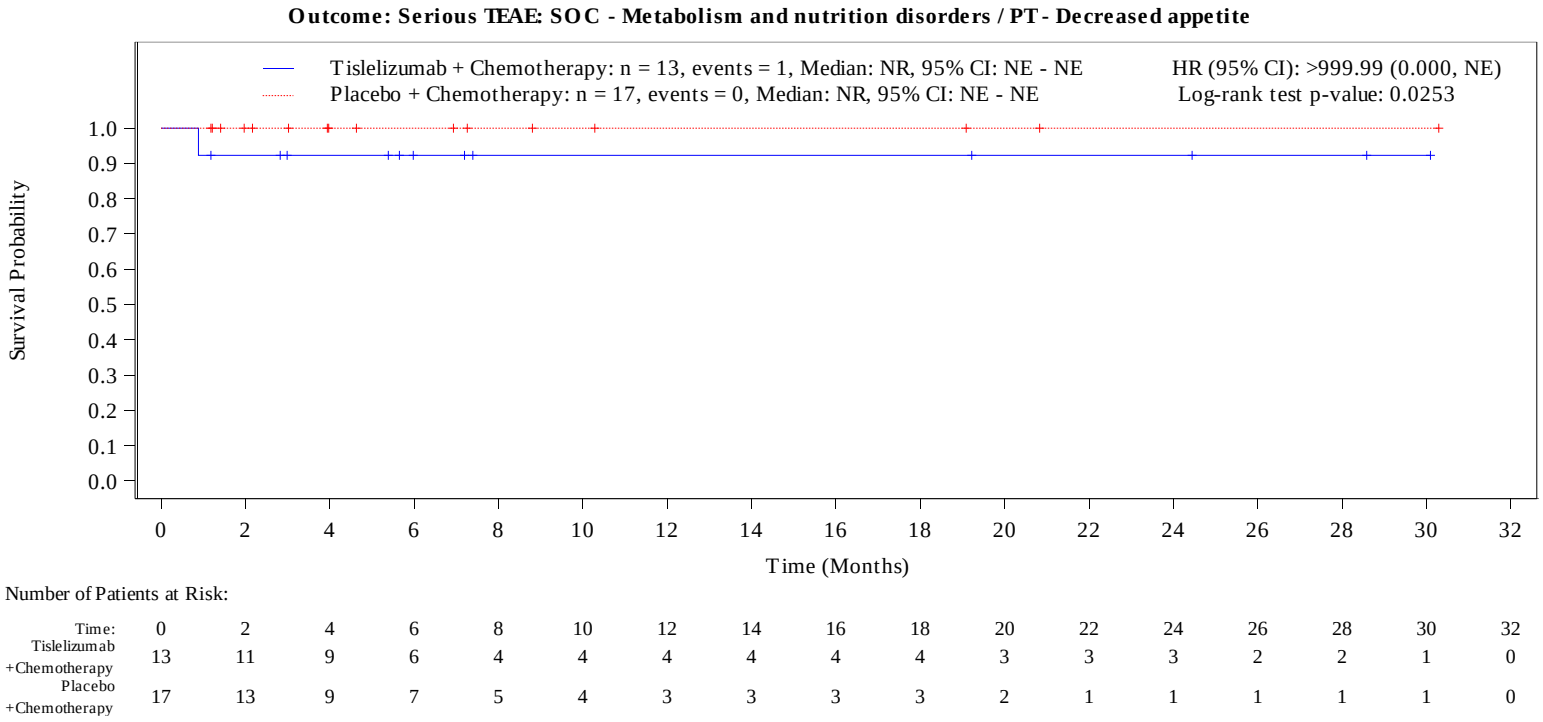

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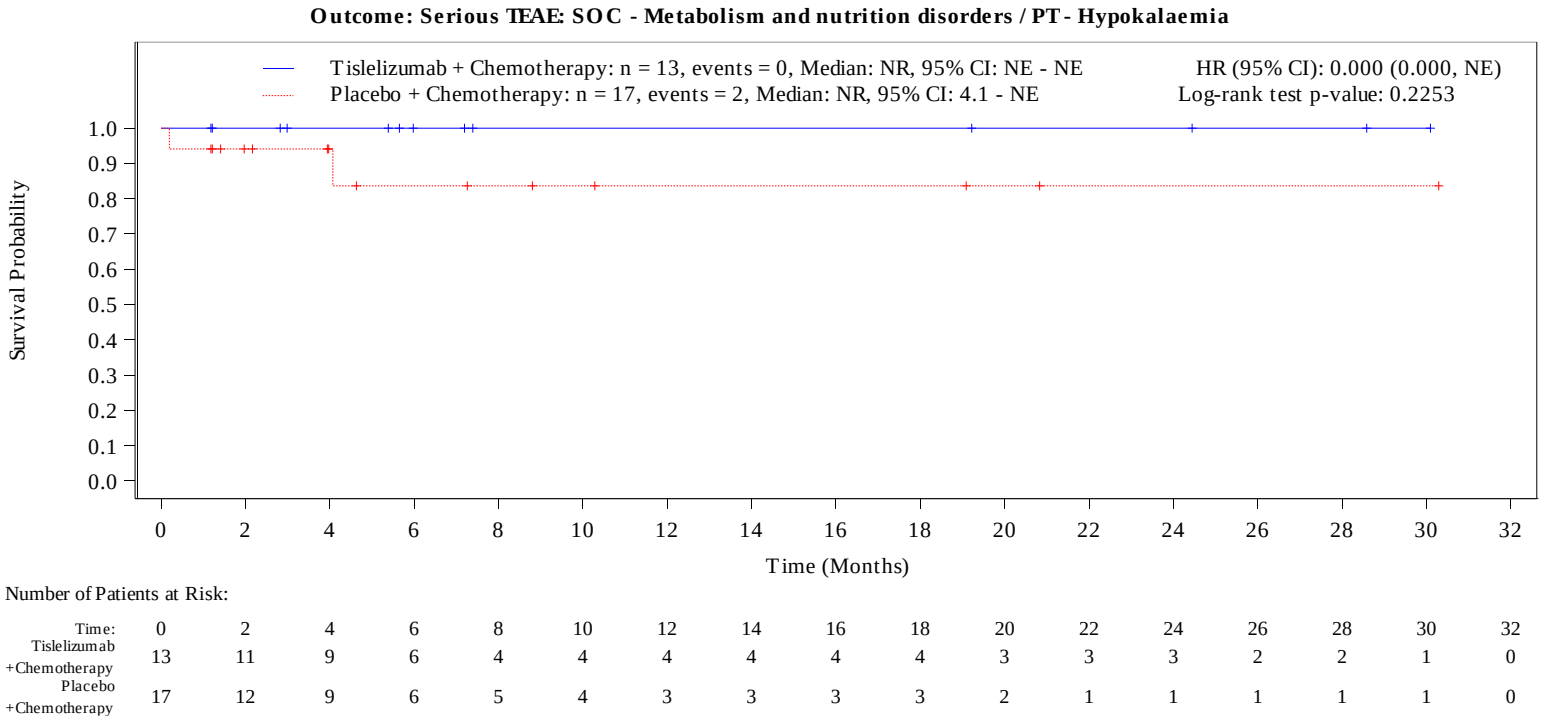

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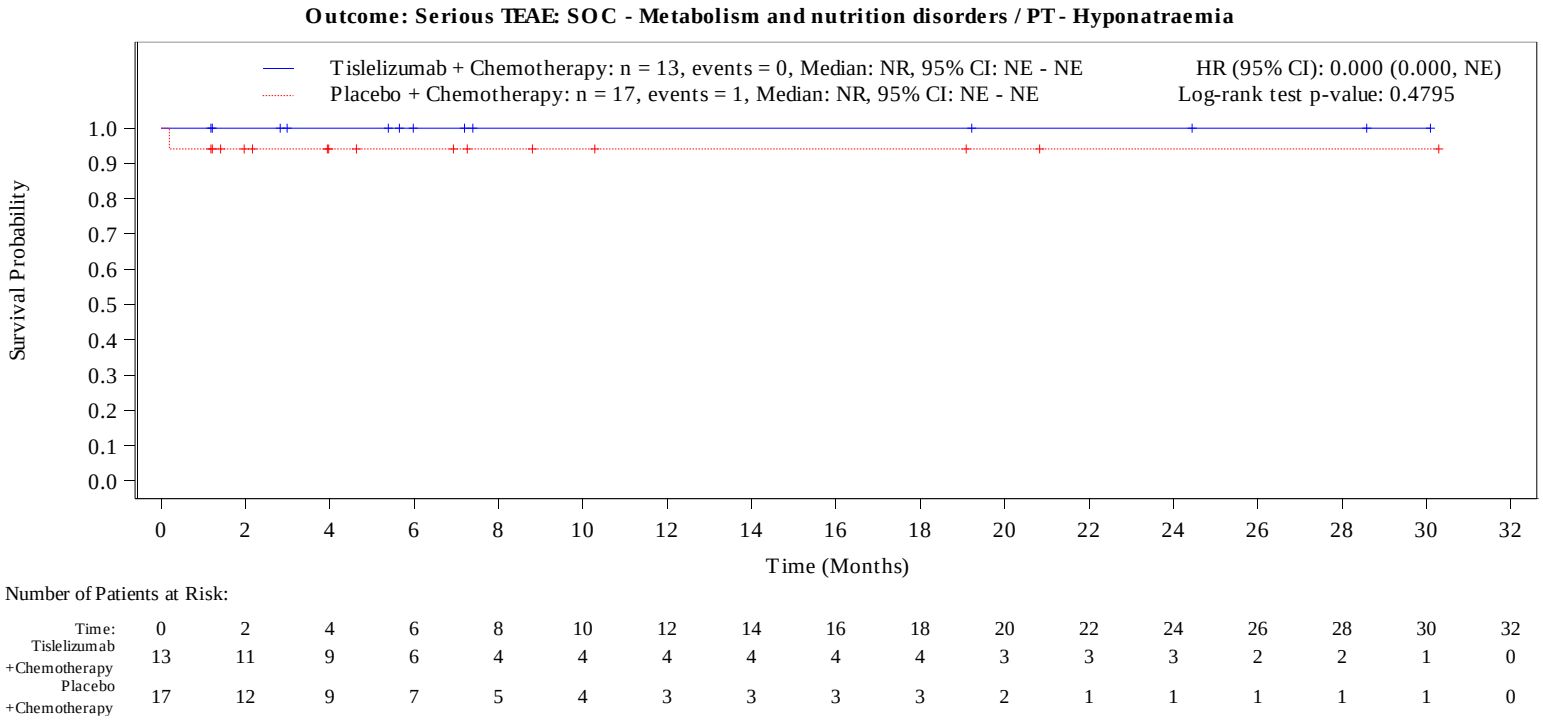

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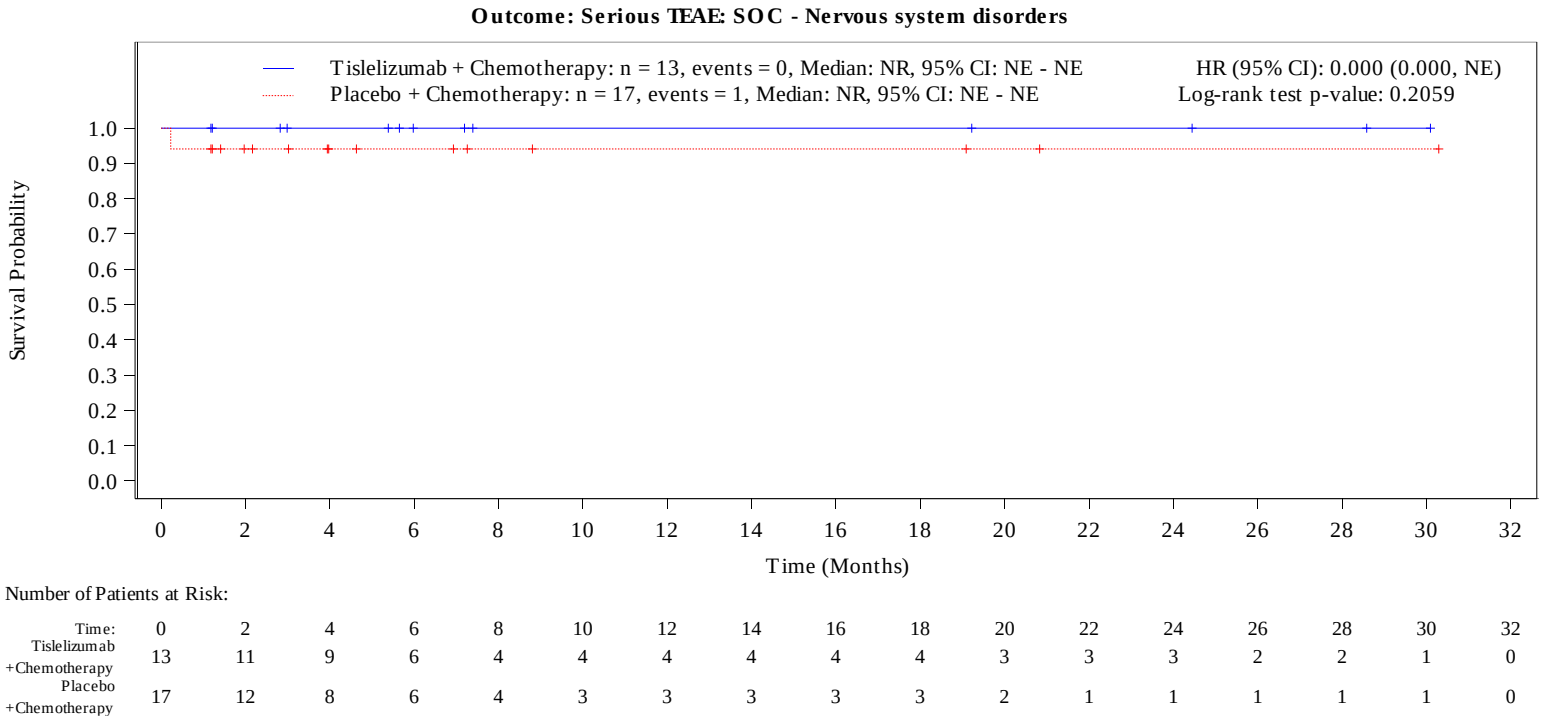

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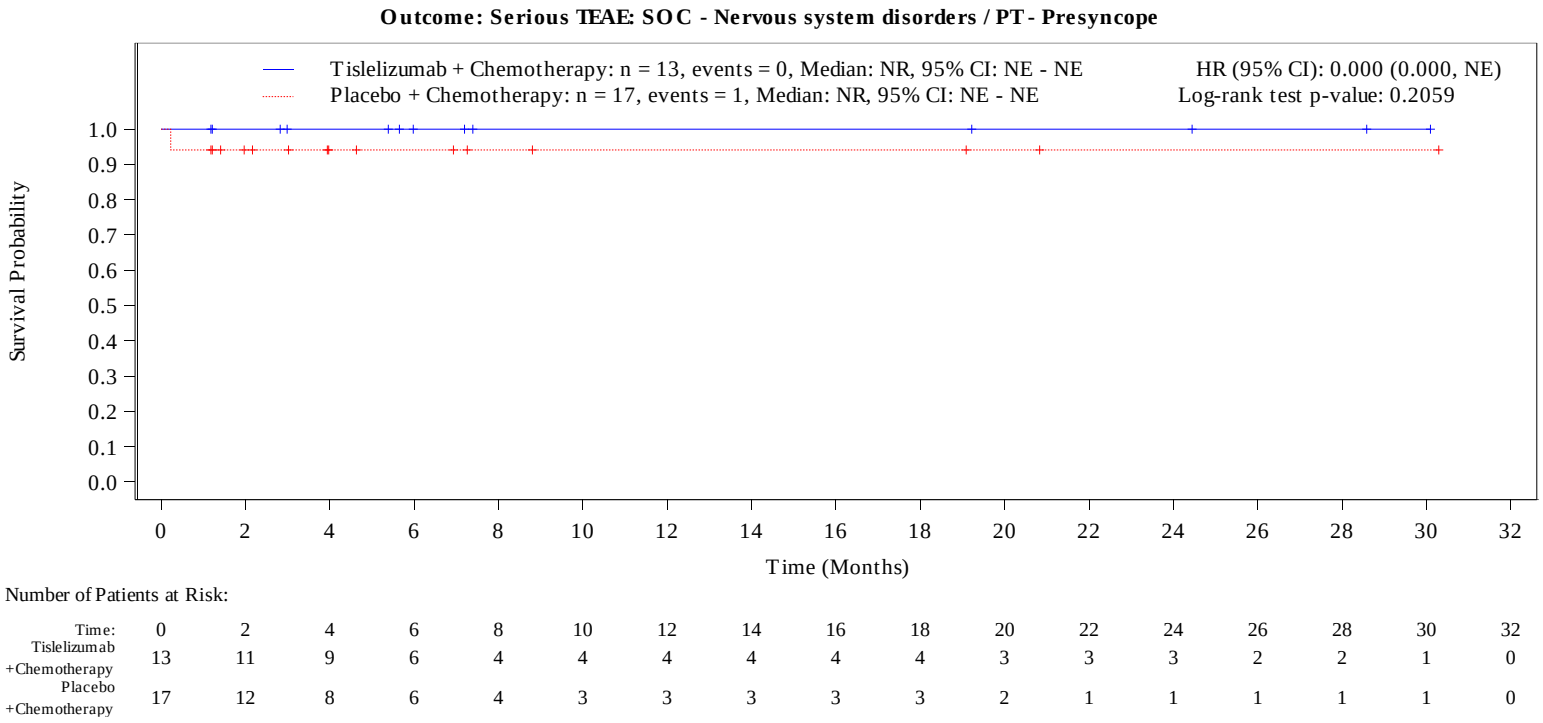

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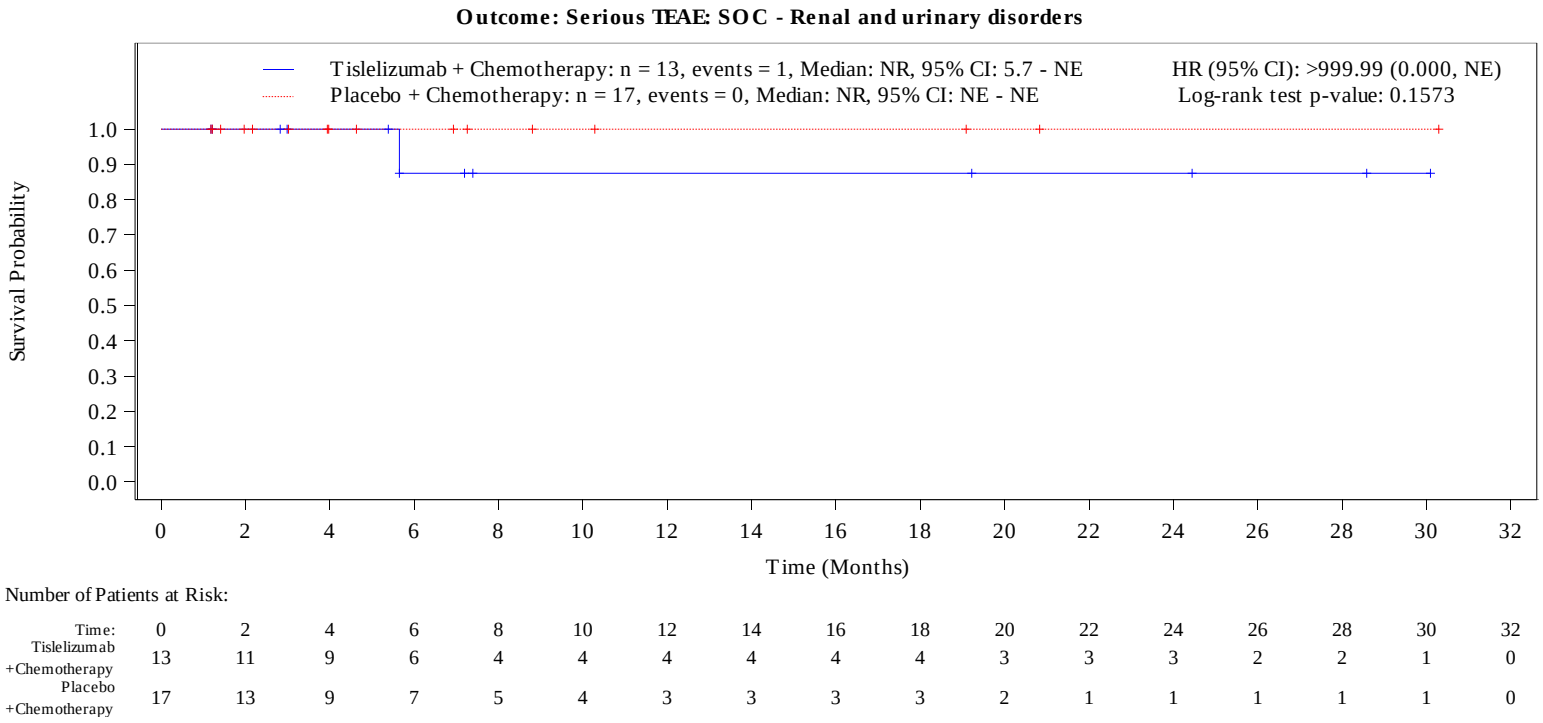

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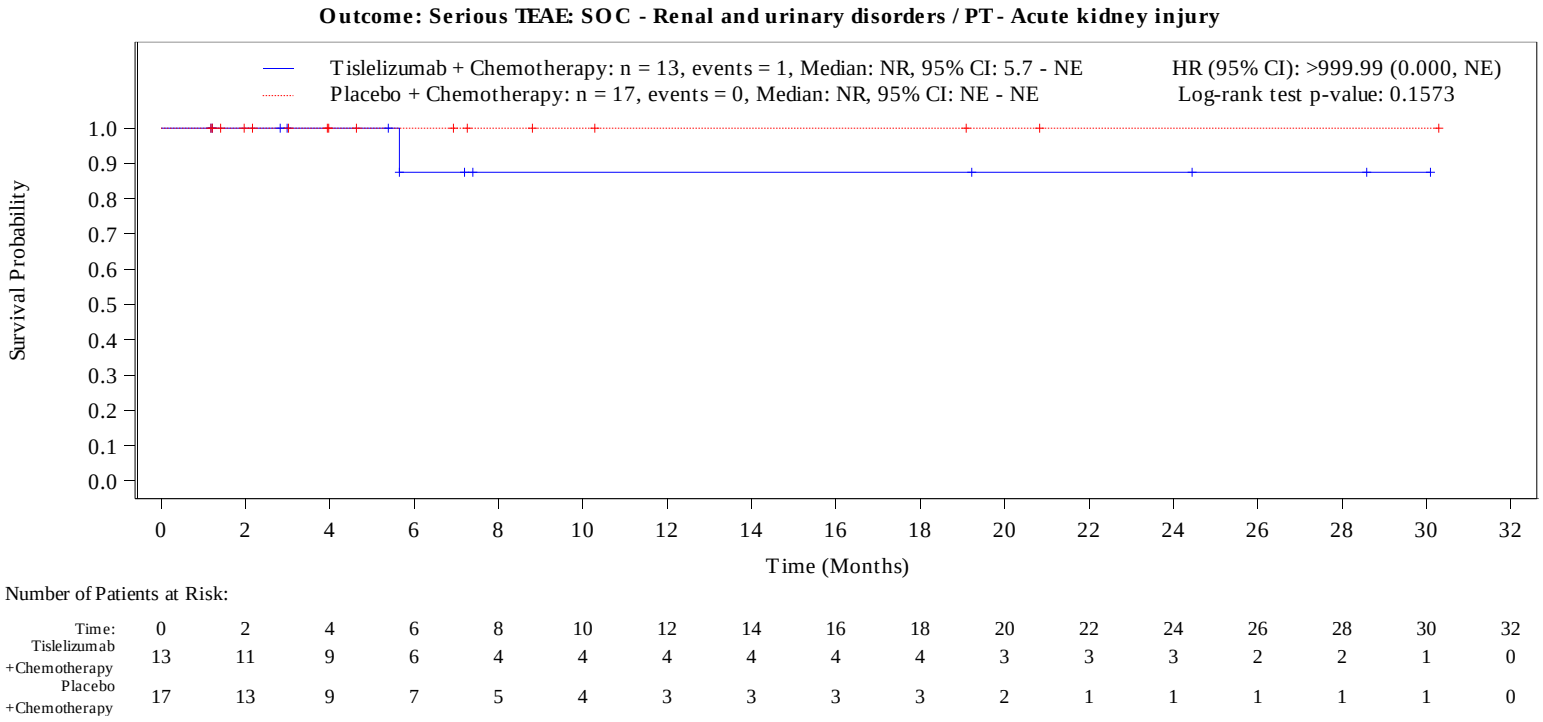
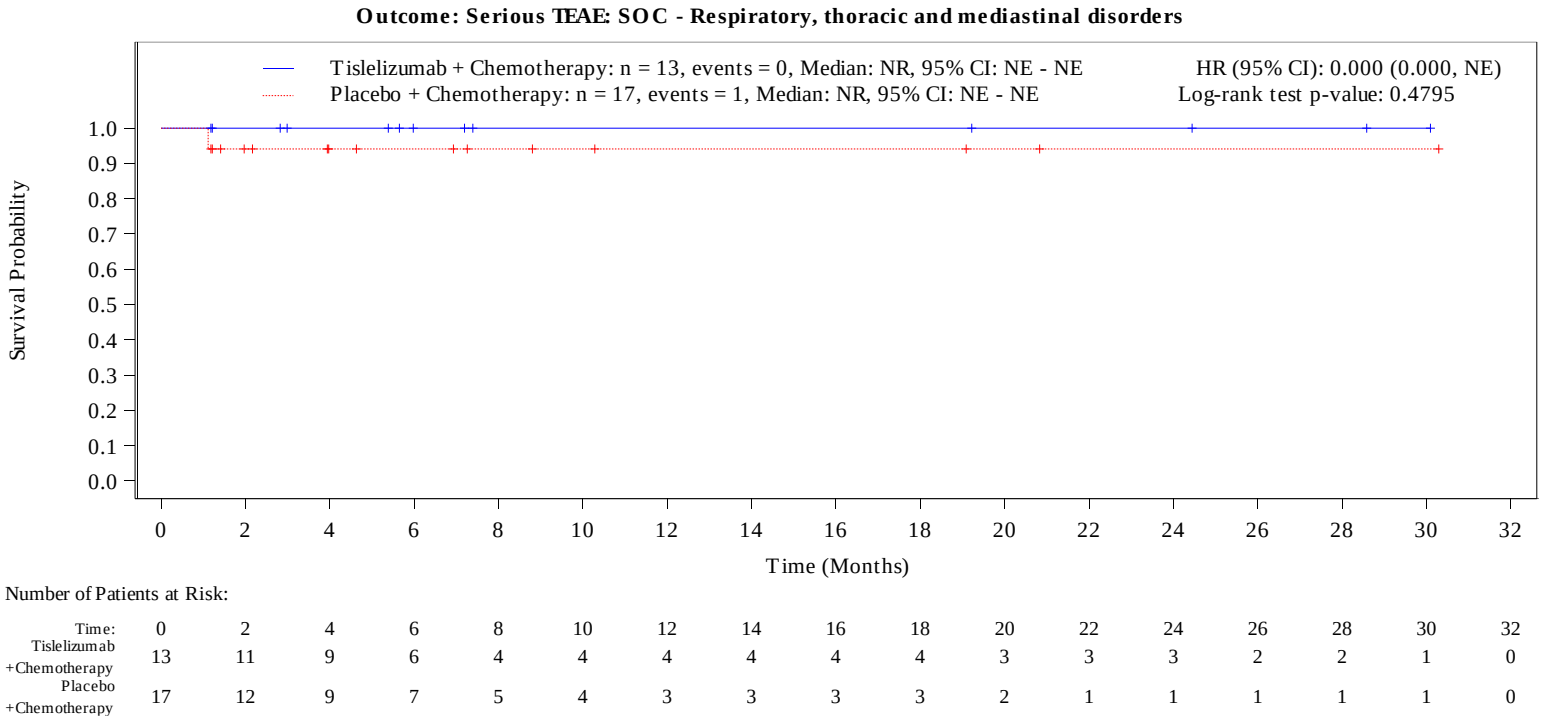


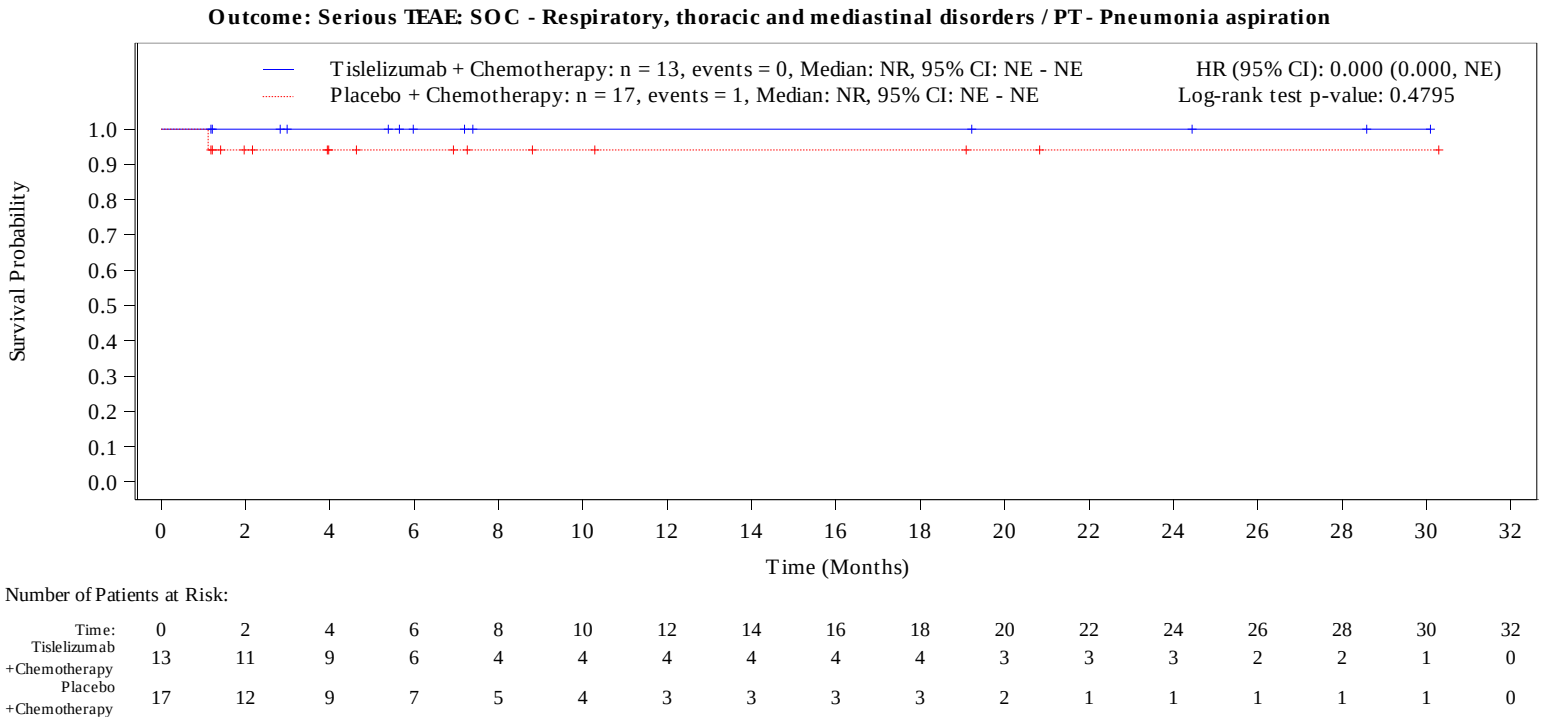
Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-4-km-aesocpt-ser-pop1-ia.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-4-km-aesocpt-ser-pop1-ia.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-4-km-aesocpt-ser-pop1-ia.rtf

Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	7 (77.8)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	6 (66.7)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	2 (20.0)	--	--	--
1	6	5 (83.3)	--	7	2 (28.6)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	--	7	2 (28.6)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	3 (50.0)	--	7	1 (14.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	4 (44.4)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	6 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	2 (50.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	6 (60.0)	--	--	--
1	6	2 (33.3)	--	7	3 (42.9)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	1 (25.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	2 (33.3)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

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Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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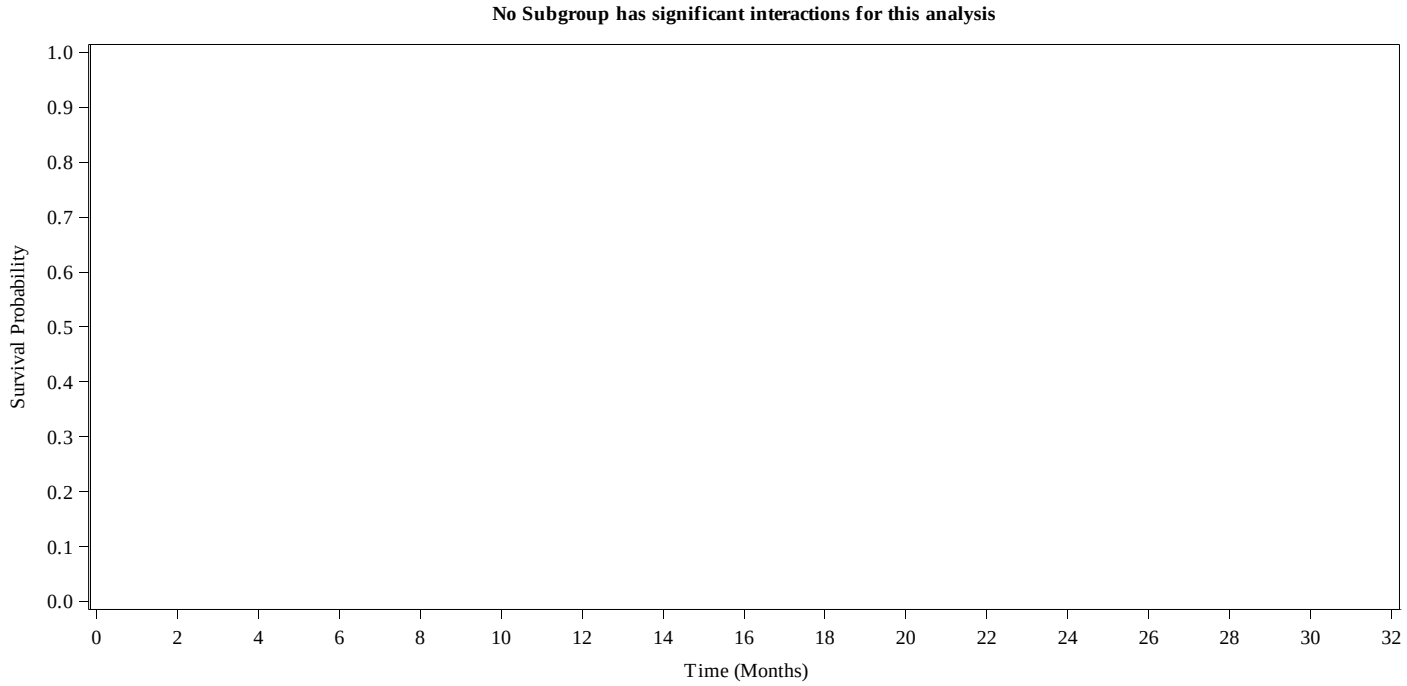
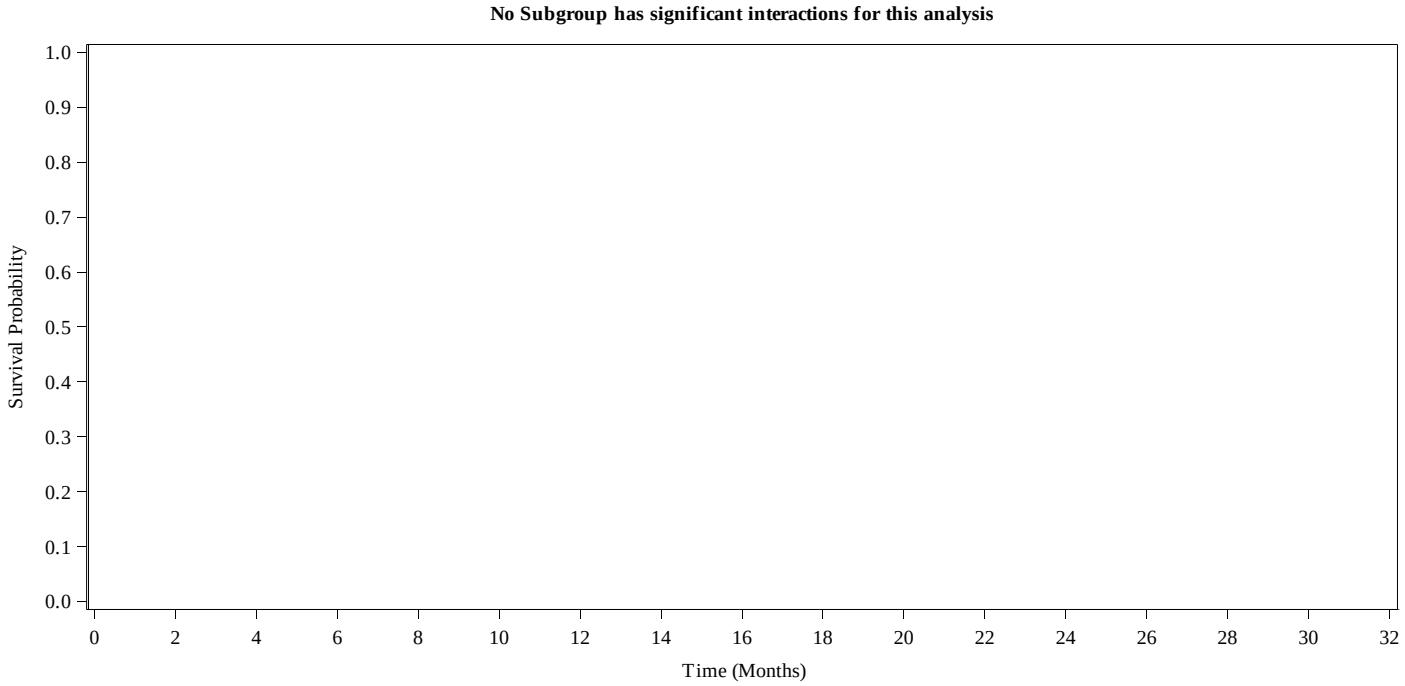
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



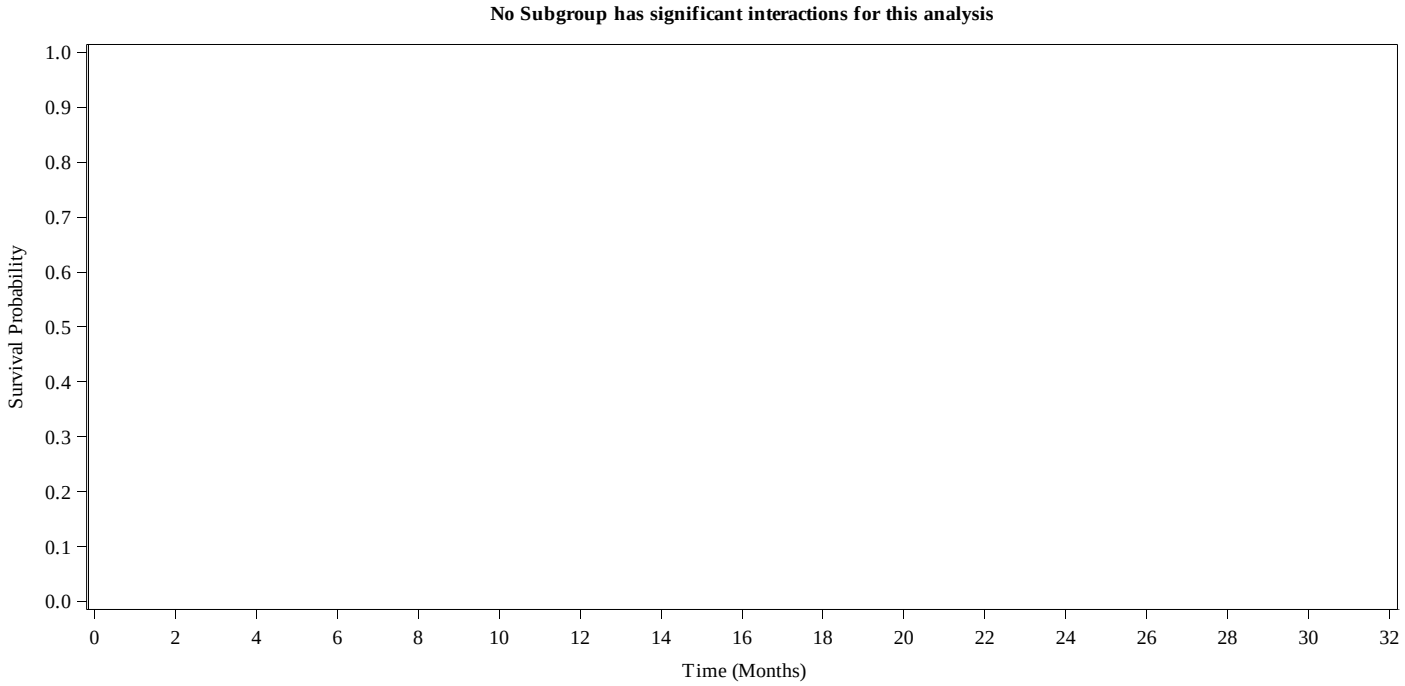
Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any imAE	13	5 (38.5)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.186 (0.261, 5.396)	0.8252
imAE of Grade 1 and 2	13	4 (30.8)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.081 (0.226, 5.165)	0.9220
imAE >= Grade 3	13	2 (15.4)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Serious imAE	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5930

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR of Grade 1 and 2	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR >= Grade 3	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Adverse events were graded for severity using CTCAE v4.03.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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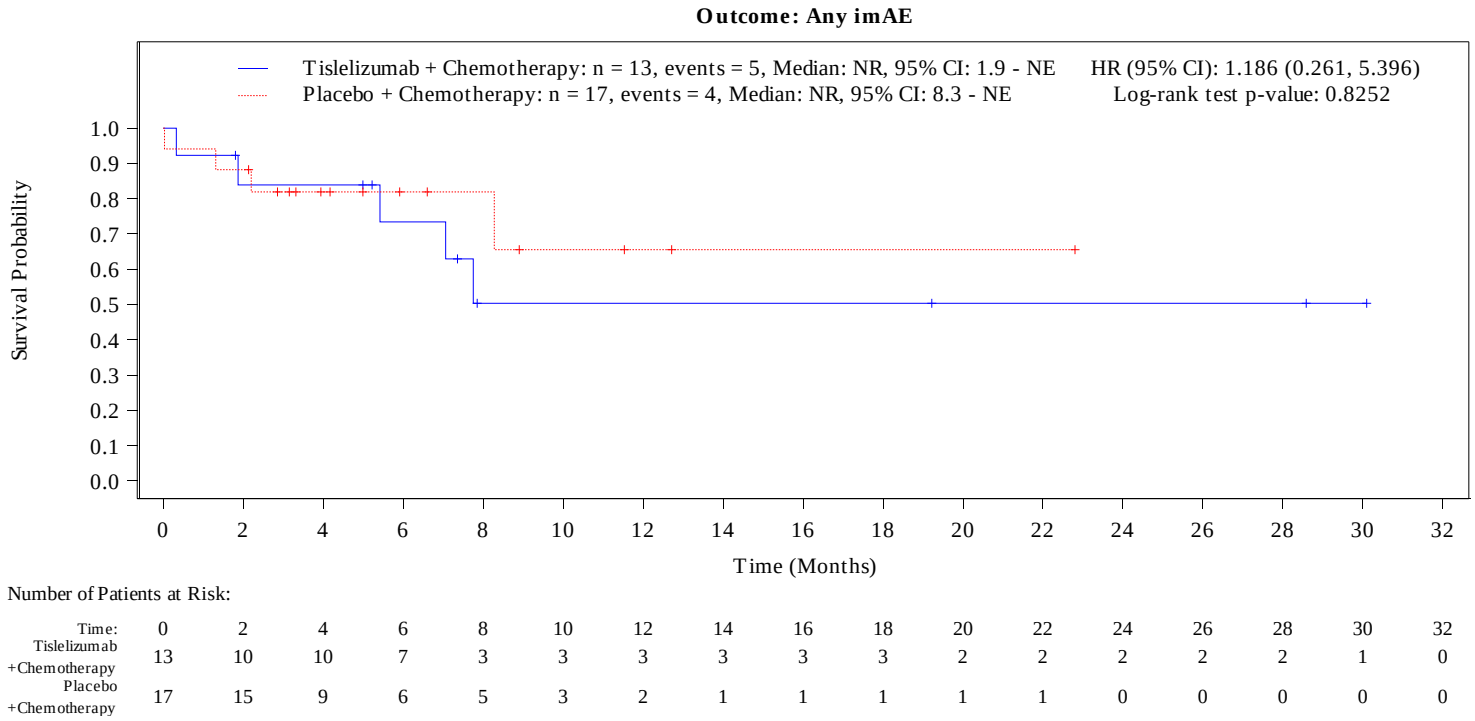
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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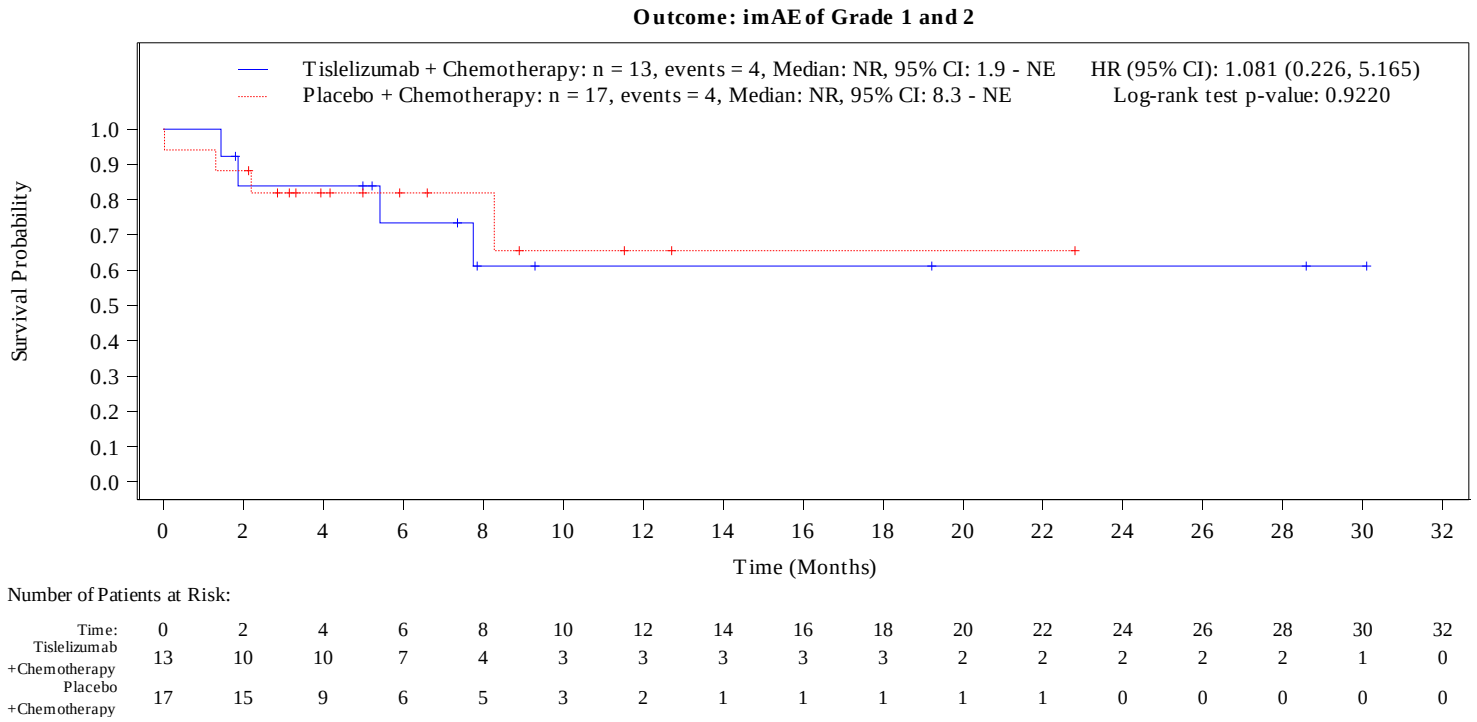
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab +Chemotherapy	13	10	10	7	4	3	3	3	3	3	2	2	2	2	2	1	0
Placebo +Chemotherapy	17	15	9	6	5	3	2	1	1	1	1	1	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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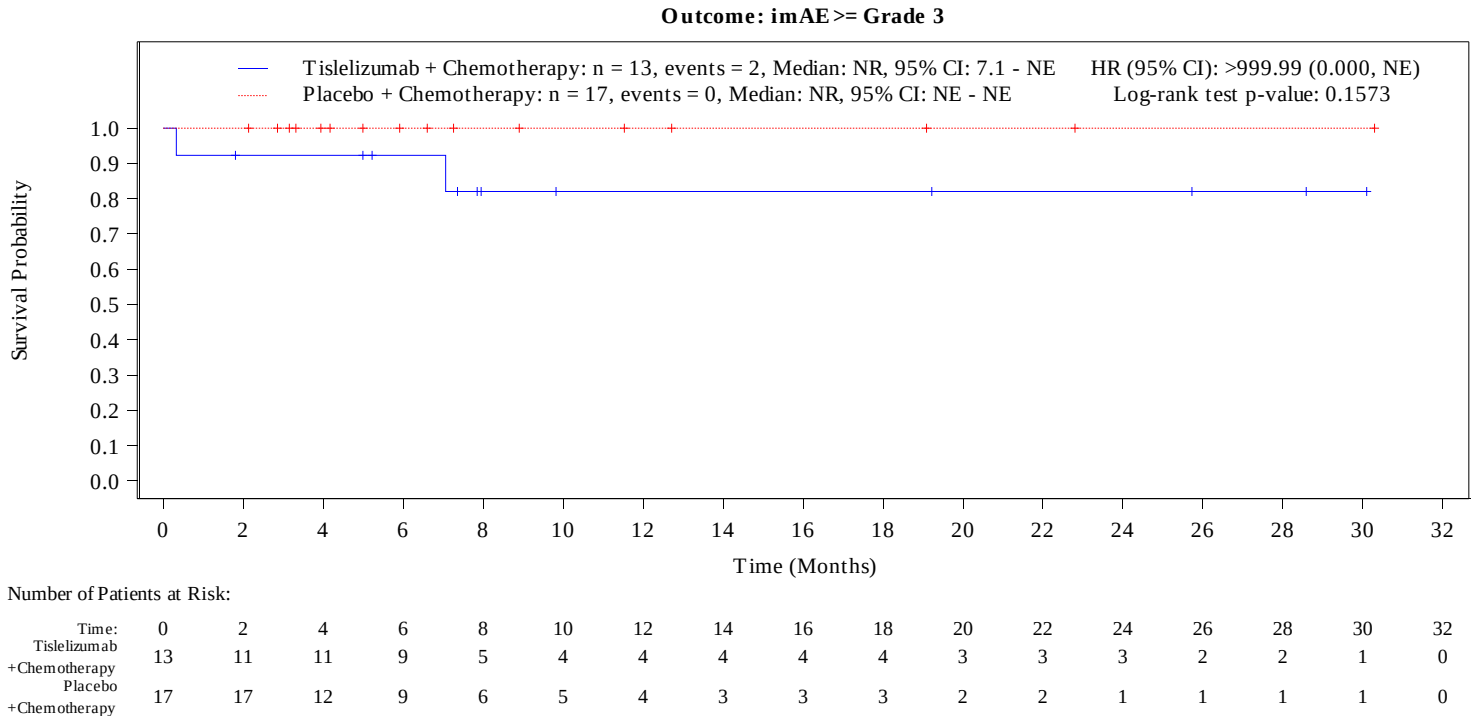
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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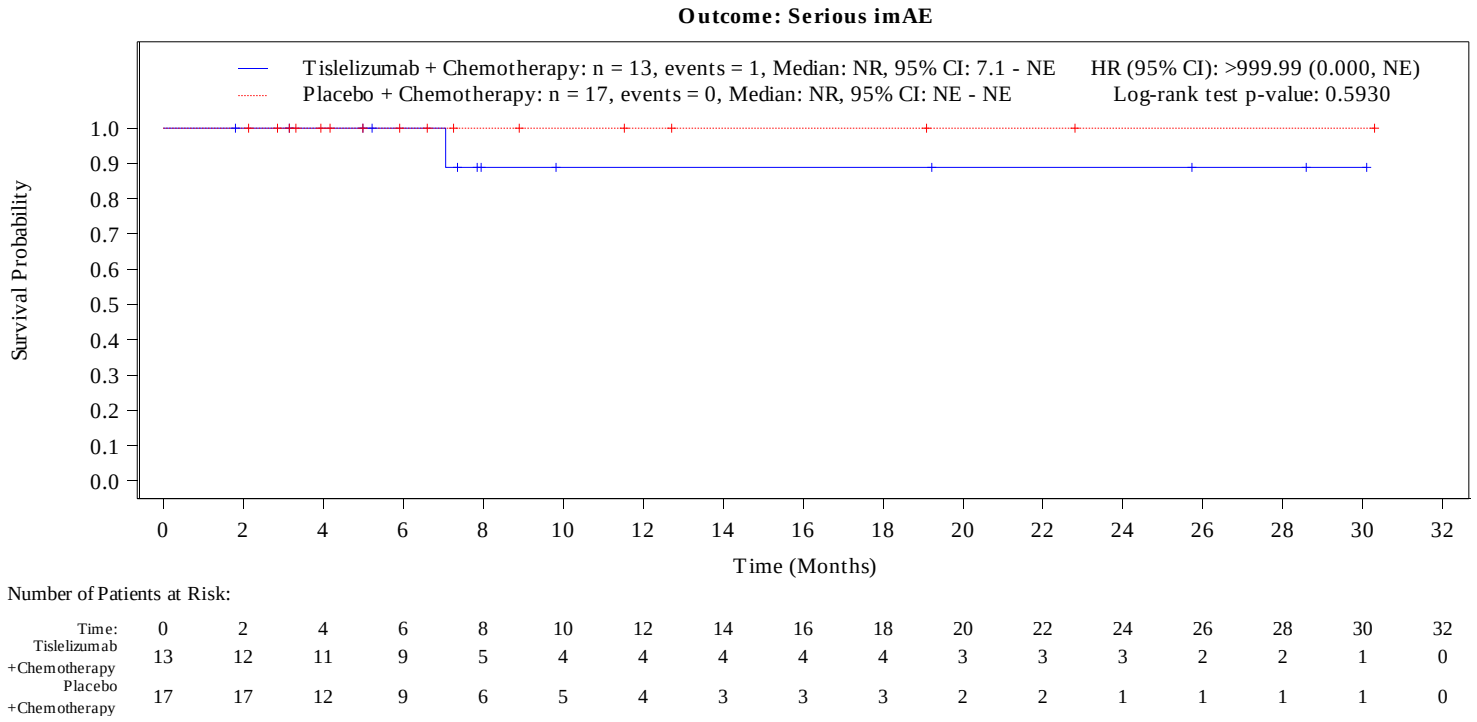
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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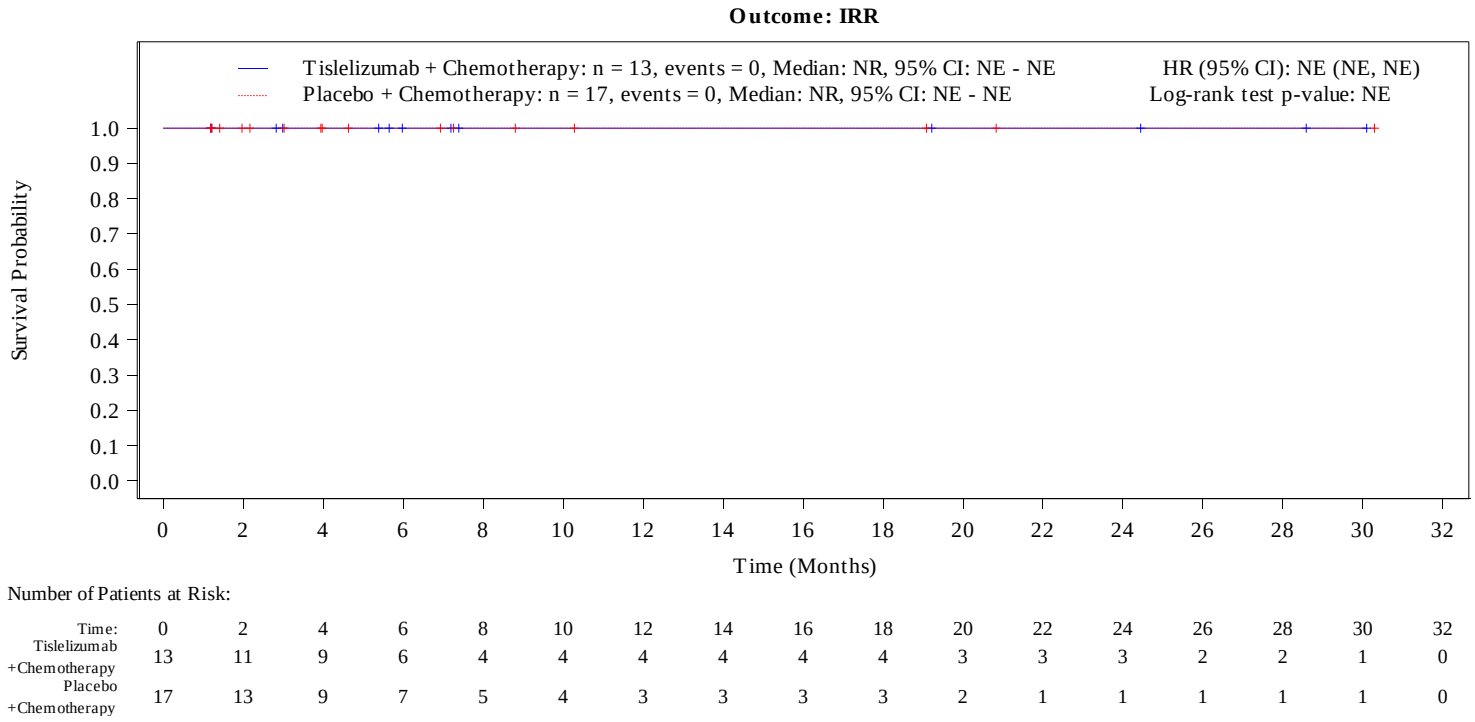
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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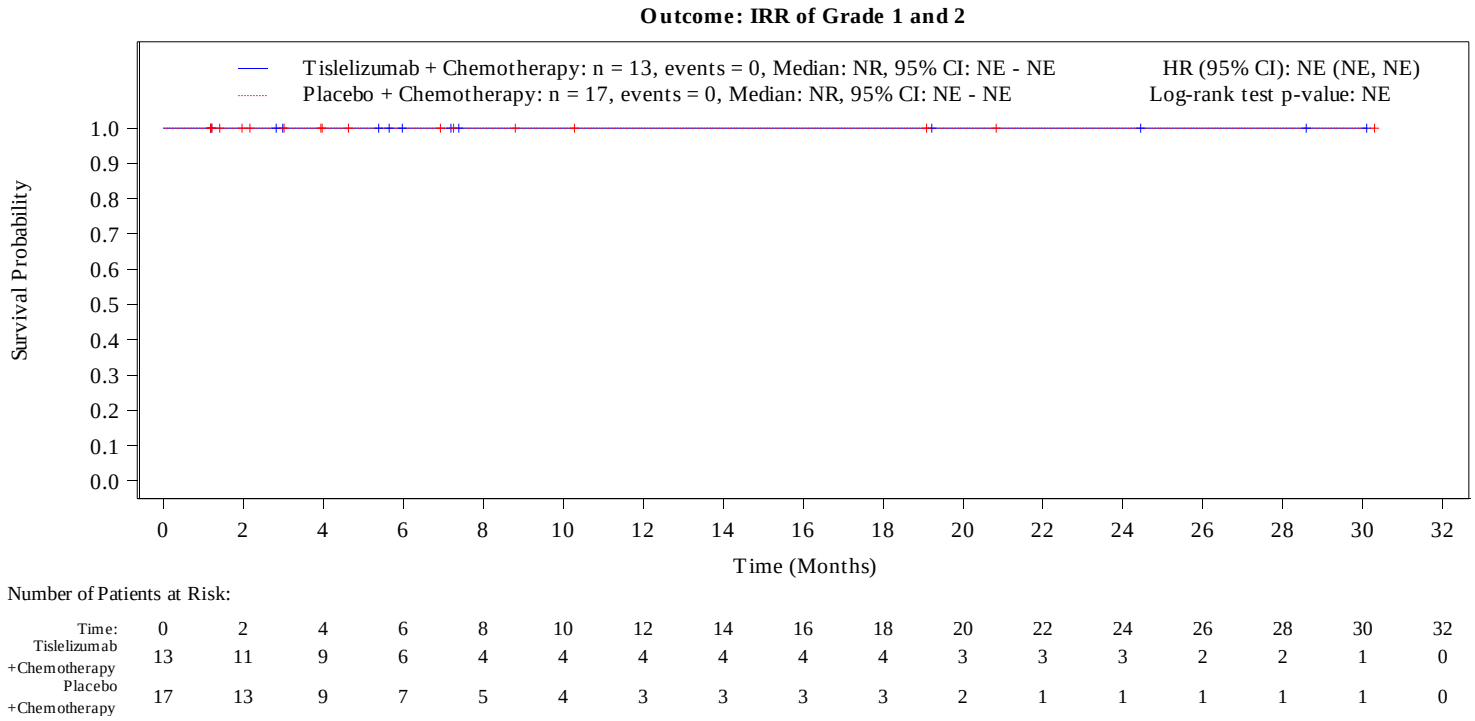
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	3	3	3	2	2	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	2	1	1	1	1	1	0

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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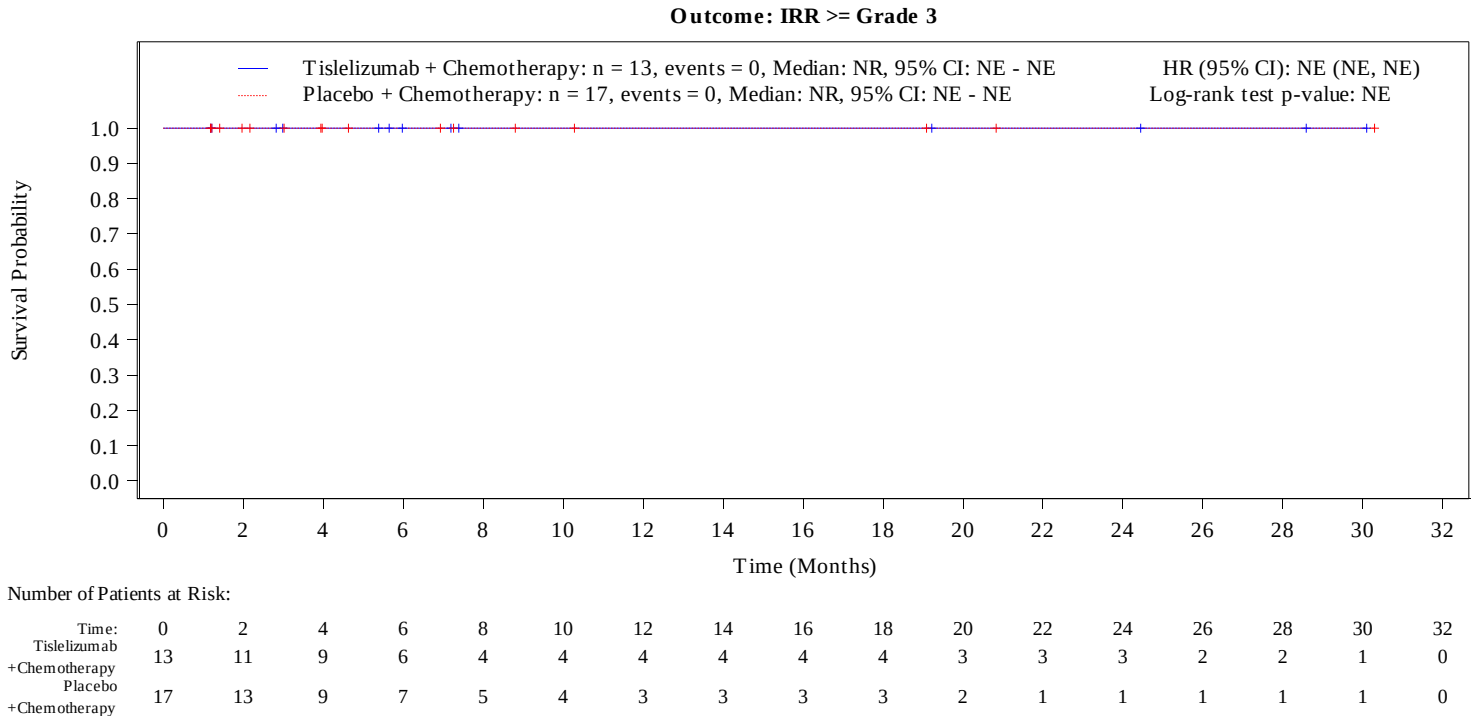
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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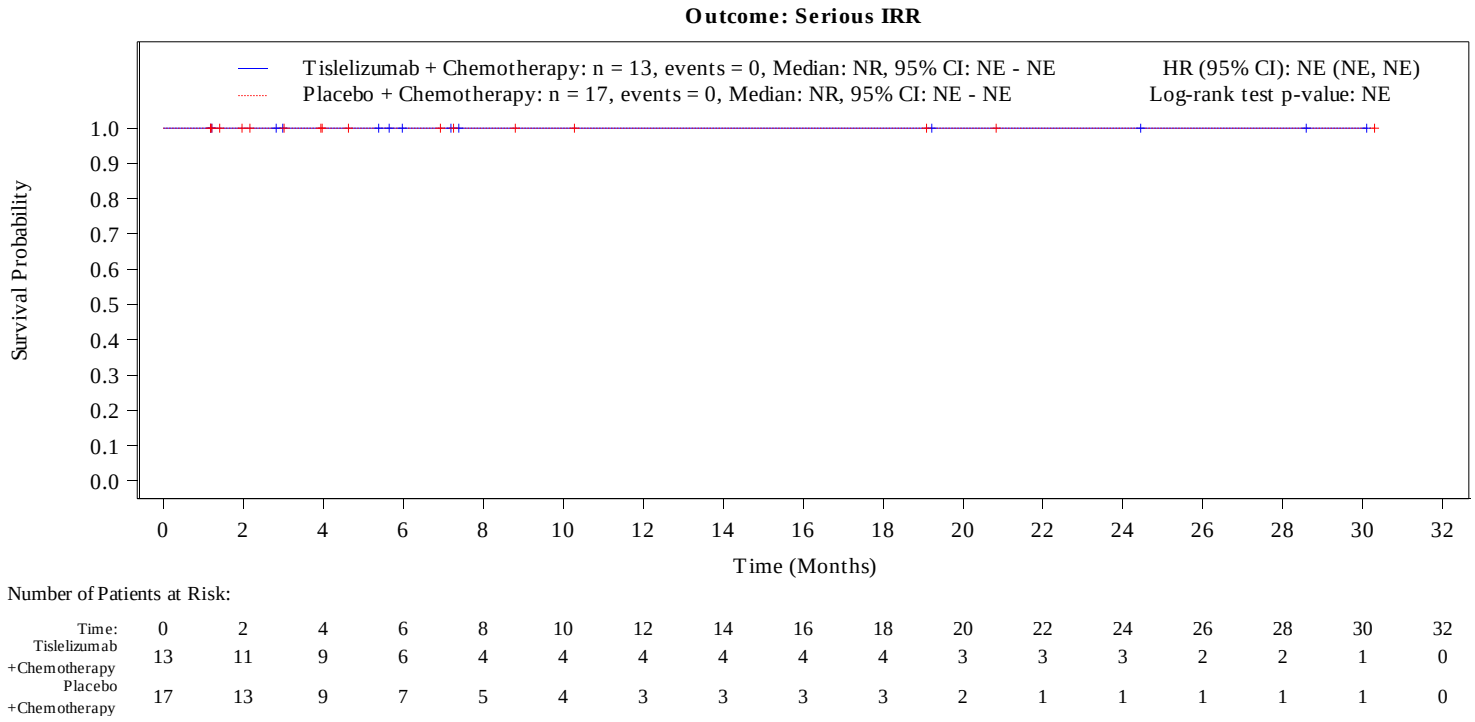
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesi.sas 21OCT2024 21:59 f-14-3-1-5-km-aesi-pop1-ia.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	3 (33.3)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	3 (33.3)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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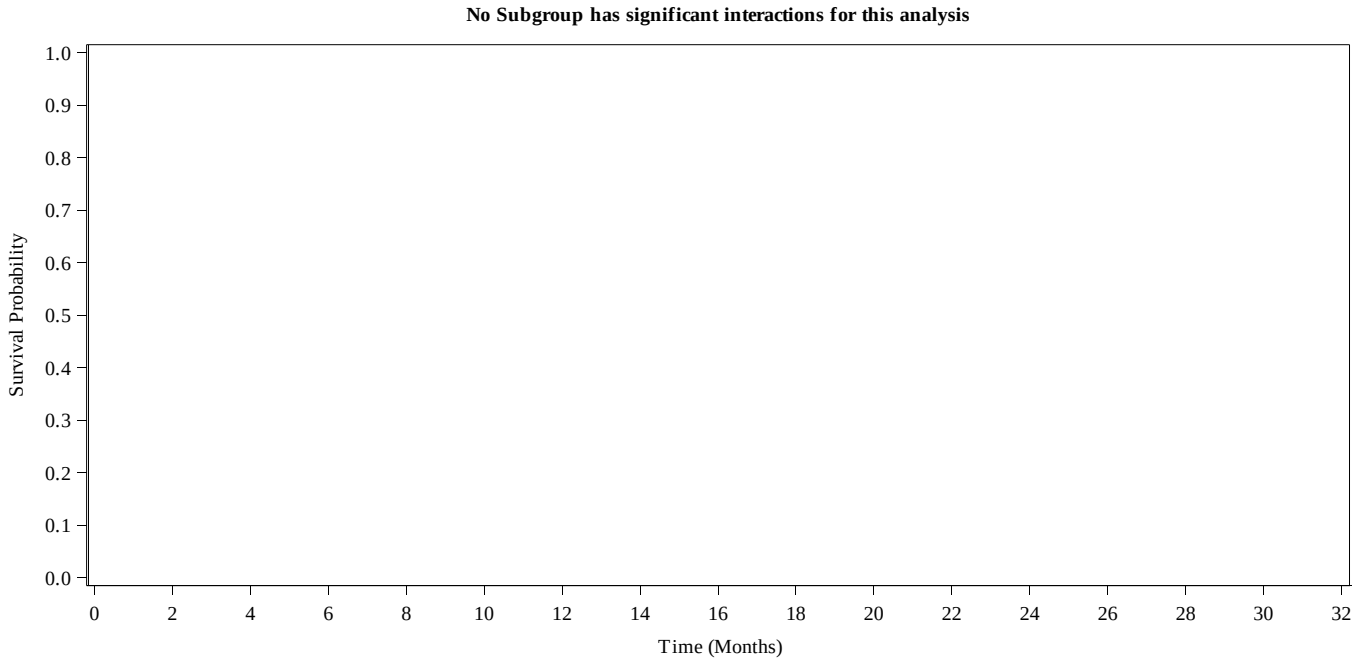
Figure 14.3.1.5.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28FEB2022. Data extraction: 06APR2022.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Adverse events were graded for severity using CTCAE v4.03. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesi-subgrp.sas 21OCT2024 21:58 f-14-3-1-5-s-km-aesi-subgrp-pop1-ia.rtf

Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Number of Patients Randomized	13 (100.0)	17 (100.0)	30 (100.0)
Patients Randomized, But not Treated	0 (0.0)	0 (0.0)	0 (0.0)
Primary Reason for not Treated [a]			
Number of Patients Treated	13 (100.0)	17 (100.0)	30 (100.0)
Number of Patients Discontinued from Treatment	12 (92.3)	17 (100.0)	29 (96.7)

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
[a] Patients randomized but not treated with any treatment component.
[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.
[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.
[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.
[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ds.sas 21OCT2024 08:29 t-14-1-1-2-1-ds-pop1-sa.rtf

Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Drug Discontinuation [b]			
Progressive Disease	7 (53.8)	12 (70.6)	19 (63.3)
Radiographic Progression	6 (46.2)	11 (64.7)	17 (56.7)
Clinical Progression	1 (7.7)	1 (5.9)	2 (6.7)
Withdrawal by Subject	3 (23.1)	2 (11.8)	5 (16.7)
Adverse Event	1 (7.7)	2 (11.8)	3 (10.0)
Treatment-interruption [c]	1 (7.7)	0 (0.0)	1 (3.3)
Other	0 (0.0)	1 (5.9)	1 (3.3)
Number of Patients Remained on Treatment	1 (7.7)	0 (0.0)	1 (3.3)
Number of Patients Discontinued from Study	7 (53.8)	13 (76.5)	20 (66.7)

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Discontinuation			
Death	7 (53.8)	11 (64.7)	18 (60.0)
Lost to Follow-up	0 (0.0)	1 (5.9)	1 (3.3)
Withdrawal by Subject	0 (0.0)	1 (5.9)	1 (3.3)
Number of Patients Remained on Study	6 (46.2)	4 (23.5)	10 (33.3)
Study Follow-up Duration [d] (months)			
n	13	17	30
Mean (SD)	26.8 (13.17)	16.3 (13.59)	20.9 (14.19)
Median	26.5	9.8	19.8
Q1, Q3	19.1, 37.9	7.0, 23.8	8.0, 33.1
Min, Max	1.8, 44.0	2.2, 44.3	1.8, 44.3

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Minimum Study Follow-Up Time [e] (months)	32.1	31.4	31.4

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Age (years)			
n	13	17	30
Mean (SD)	59.7 (7.48)	65.1 (7.94)	62.8 (8.08)
Median	60.0	66.0	62.5
Q1, Q3	57.0, 65.0	59.0, 72.0	58.0, 69.0
Min, Max	46, 69	47, 76	46, 76
Age Group, n (%)			
< 65 years	9 (69.2)	8 (47.1)	17 (56.7)
≥ 65 years	4 (30.8)	9 (52.9)	13 (43.3)
Sex, n (%)			
Female	4 (30.8)	6 (35.3)	10 (33.3)
Male	9 (69.2)	11 (64.7)	20 (66.7)
Region, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Asia (excluding Japan)	6 (46.2)	2 (11.8)	8 (26.7)
Japan	5 (38.5)	9 (52.9)	14 (46.7)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-dm.sas 21OCT2024 08:31 t-14-1-2-1-dm-pop1-sa.rtf

Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Race, n (%)			
Asian	11 (84.6)	11 (64.7)	22 (73.3)
Chinese	5 (38.5)	1 (5.9)	6 (20.0)
Japanese	5 (38.5)	9 (52.9)	14 (46.7)
Korean	1 (7.7)	1 (5.9)	2 (6.7)
White	2 (15.4)	5 (29.4)	7 (23.3)
American Indian or Alaska Native	0 (0.0)	1 (5.9)	1 (3.3)
Ethnicity, n (%)			
Hispanic or Latino	0 (0.0)	1 (5.9)	1 (3.3)
Not Hispanic or Latino	13 (100.0)	16 (94.1)	29 (96.7)
ECOG Status, n (%)			
0	7 (53.8)	10 (58.8)	17 (56.7)
1	6 (46.2)	7 (41.2)	13 (43.3)

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-dm.sas 21OCT2024 08:31 t-14-1-2-1-dm-pop1-sa.rtf

Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
BMI (kg/m^2)			
n	13	17	30
Mean (SD)	21.92 (3.553)	21.20 (3.497)	21.51 (3.479)
Median	21.63	20.91	21.40
Q1, Q3	21.10, 22.86	19.20, 23.31	20.20, 23.31
Min, Max	14.3, 28.3	15.9, 29.2	14.3, 29.2
Tobacco Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	9 (69.2)	12 (70.6)	21 (70.0)
Current	1 (7.7)	1 (5.9)	2 (6.7)
Alcohol Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	8 (61.5)	10 (58.8)	18 (60.0)
Current	2 (15.4)	2 (11.8)	4 (13.3)
Missing	0 (0.0)	1 (5.9)	1 (3.3)
Pooled Geographic Region per IRT, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-dm.sas 21OCT2024 08:31 t-14-1-2-1-dm-pop1-sa.rtf

Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Definitive Therapy per IRT, n (%)			
Yes	4 (30.8)	7 (41.2)	11 (36.7)
No	9 (69.2)	10 (58.8)	19 (63.3)

Source: ADSL. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-dm.sas 21OCT2024 08:31 t-14-1-2-1-dm-pop1-sa.rtf

Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Time from Initial Diagnosis to Study Entry (months)			
n	13	17	30
Mean (SD)	8.30 (16.077)	8.16 (15.719)	8.22 (15.598)
Median	0.95	1.81	1.12
Q1, Q3	0.76, 12.48	0.82, 11.10	0.76, 12.09
Min, Max	0.5, 58.2	0.2, 65.7	0.2, 65.7
Primary Site of Esophageal Cancer, n (%)			
Cervical	0 (0.0)	3 (17.6)	3 (10.0)
Upper thoracic	5 (38.5)	4 (23.5)	9 (30.0)
Middle thoracic	4 (30.8)	5 (29.4)	9 (30.0)
Lower thoracic	4 (30.8)	5 (29.4)	9 (30.0)

Source: ADSL, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-dh.sas 21OCT2024 08:28 t-14-1-3-1-dh-pop1-sa.rtf

Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Histologic Grade, n (%)			
Gx - Grade cannot be assessed	5 (38.5)	8 (47.1)	13 (43.3)
G1 - Well-differentiated	1 (7.7)	2 (11.8)	3 (10.0)
G2 - Moderately-differentiated	6 (46.2)	6 (35.3)	12 (40.0)
G3 - Poorly differentiated	1 (7.7)	1 (5.9)	2 (6.7)
Histologic Type, n (%)			
Squamous Cell Carcinoma	13 (100.0)	17 (100.0)	30 (100.0)
Other [a]	0 (0.0)	0 (0.0)	0 (0.0)
Disease Stage at Diagnosis [b], n (%)			
Stage I (IA, IB)	1 (7.7)	1 (5.9)	2 (6.7)
Stage II (IIA, IIB)	1 (7.7)	2 (11.8)	3 (10.0)
Stage III (IIIA, IIIB, IIIC)	3 (23.1)	5 (29.4)	8 (26.7)
Stage IV	8 (61.5)	9 (52.9)	17 (56.7)

Source: ADSL, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.

Study Entry date referred to randomization date in this study.

[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.

[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.

[c] A patient was counted only once within each category, but may be counted in multiple categories.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Disease Status at Study Entry, n (%)			
Metastatic	12 (92.3)	15 (88.2)	27 (90.0)
Locally Advanced	1 (7.7)	2 (11.8)	3 (10.0)
Time from Metastatic Disease to Study Entry (months)			
n	12	15	27
Mean (SD)	1.30 (1.812)	3.51 (10.275)	2.53 (7.713)
Median	0.74	0.72	0.72
Q1, Q3	0.53, 1.33	0.33, 1.38	0.46, 1.35
Min, Max	0.3, 6.9	0.0, 40.6	0.0, 40.6
Number of Metastatic Sites at Study Entry, n (%)			
0	1 (7.7)	2 (11.8)	3 (10.0)
1	9 (69.2)	8 (47.1)	17 (56.7)
2	2 (15.4)	5 (29.4)	7 (23.3)
>2	1 (7.7)	2 (11.8)	3 (10.0)

Source: ADSL, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Locations of Metastases at Study Entry [c], n (%)			
Lymph Nodes	7 (53.8)	6 (35.3)	13 (43.3)
Lung	6 (46.2)	7 (41.2)	13 (43.3)
Liver	2 (15.4)	4 (23.5)	6 (20.0)
Bone	1 (7.7)	1 (5.9)	2 (6.7)
Brain	0 (0.0)	0 (0.0)	0 (0.0)
Peritoneum	0 (0.0)	0 (0.0)	0 (0.0)
Skin	0 (0.0)	0 (0.0)	0 (0.0)
Soft Tissue	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	6 (35.3)	6 (20.0)

Source: ADSL, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Target Lesions Sum of Diameter by Investigator (mm)			
n	13	15	28
Mean (SD)	30.95 (18.422)	54.19 (28.241)	43.40 (26.527)
Median	27.20	54.62	31.00
Q1, Q3	17.00, 43.20	27.00, 75.00	21.35, 62.36
Min, Max	10.4, 67.0	18.8, 109.0	10.4, 109.0
PD-L1 Status, n (%)			
PD-L1 Score < 10%	13 (100.0)	17 (100.0)	30 (100.0)

Source: ADSL, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.

Study Entry date referred to randomization date in this study.

[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.

[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.

[c] A patient was counted only once within each category, but may be counted in multiple categories.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Patients with at Least One Prior Definitive Therapy, n (%) [a]	4 (30.8)	7 (41.2)	11 (36.7)
Definitive Radiotherapy with/without Chemotherapy	0 (0.0)	1 (5.9)	1 (3.3)
Definitive Surgery with/without Adjuvant/Neo-adjuvant Treatment	4 (30.8)	6 (35.3)	10 (33.3)
Time from End of Last Prior Anti-Cancer Therapy to Study Entry [b] (months)			
n	4	8	12
Mean (SD)	22.71 (23.656)	30.69 (58.484)	28.03 (48.422)
Median	13.27	9.82	10.12
Q1, Q3	9.56, 35.86	7.39, 18.07	7.39, 19.81
Min, Max	6.4, 57.9	0.6, 174.4	0.6, 174.4
Prior Anti-Cancer Systemic Therapy, n (%)	2 (15.4)	5 (29.4)	7 (23.3)
Platinum Based Prior Anti-Cancer Systemic Therapy			
Yes	2 (15.4)	5 (29.4)	7 (23.3)
No	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Treatment Setting of Prior Anti-Cancer Systemic Therapies, n (%) [a]			
Neo-adjuvant Setting	2 (15.4)	4 (23.5)	6 (20.0)
Adjuvant Setting	1 (7.7)	0 (0.0)	1 (3.3)
In Combination with Definitive Radiotherapy	0 (0.0)	2 (11.8)	2 (6.7)
Duration of Last Prior Anti-Cancer Systemic Therapy (months)			
n	2	5	7
Mean (SD)	1.81 (1.254)	2.24 (1.291)	2.12 (1.191)
Median	1.81	1.81	1.81
Q1, Q3	0.92, 2.69	1.58, 2.50	0.99, 2.69
Min, Max	0.9, 2.7	1.0, 4.3	0.9, 4.3

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

[a] A patient was counted only once within each category but may be counted in multiple categories.

[b] Study Entry date referred to randomization date in this study.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Radiotherapy, n (%)	1 (7.7)	3 (17.6)	4 (13.3)
Site Irradiated, n (%) [a]			
Brain	0 (0.0)	1 (5.9)	1 (3.3)
Lung - left	0 (0.0)	0 (0.0)	0 (0.0)
Lung - right	0 (0.0)	0 (0.0)	0 (0.0)
Liver	0 (0.0)	0 (0.0)	0 (0.0)
Esophagus	0 (0.0)	1 (5.9)	1 (3.3)
Head and neck	0 (0.0)	0 (0.0)	0 (0.0)
Stomach	0 (0.0)	0 (0.0)	0 (0.0)
Retroperitoneum	1 (7.7)	0 (0.0)	1 (3.3)
Bone	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Anti-Cancer Surgery, n (%)	4 (30.8)	7 (41.2)	11 (36.7)
Surgical Procedure, n (%) [a]			
Esophagectomy - Upper	0 (0.0)	3 (17.6)	3 (10.0)
Esophagectomy - Middle	2 (15.4)	1 (5.9)	3 (10.0)
Esophagectomy - Lower	2 (15.4)	2 (11.8)	4 (13.3)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Prior Medication	7 (53.8)	8 (47.1)	15 (50.0)
Amides	2 (15.4)	1 (5.9)	3 (10.0)
Lidocaine	2 (15.4)	1 (5.9)	3 (10.0)
Third-Generation Cephalosporins	2 (15.4)	0 (0.0)	2 (6.7)
Cefditoren Pivoxil	1 (7.7)	0 (0.0)	1 (3.3)
Cefotaxime Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids	1 (7.7)	0 (0.0)	1 (3.3)
Tranexamic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Anesthetics, Local	1 (7.7)	0 (0.0)	1 (3.3)
Dyclonine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Anilides	1 (7.7)	1 (5.9)	2 (6.7)
Paracetamol	1 (7.7)	1 (5.9)	2 (6.7)
Benzodiazepine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Amoxicillin;clavulanic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Contact Laxatives	1 (7.7)	0 (0.0)	1 (3.3)
Sennoside A+b Calcium	1 (7.7)	0 (0.0)	1 (3.3)
Fluoroquinolones	1 (7.7)	0 (0.0)	1 (3.3)
Levofloxacin	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
H2-Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Famotidine	1 (7.7)	0 (0.0)	1 (3.3)
Natural Opium Alkaloids	1 (7.7)	0 (0.0)	1 (3.3)
Hydromorphone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	0 (0.0)	1 (3.3)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	0 (0.0)	1 (3.3)
Aldioxa	1 (7.7)	0 (0.0)	1 (3.3)
Proton Pump Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Esomeprazole Sodium	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	1 (7.7)	2 (11.8)	3 (10.0)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Unspecified Herbal And Traditional Medicine	1 (7.7)	0 (0.0)	1 (3.3)
Ginkgo Biloba Extract	1 (7.7)	0 (0.0)	1 (3.3)
Vitamin B1, Plain	1 (7.7)	0 (0.0)	1 (3.3)
Cetotiamine	1 (7.7)	0 (0.0)	1 (3.3)
Acetic Acid Derivatives And Related Substances	0 (0.0)	2 (11.8)	2 (6.7)
Aceclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Ketorolac Tromethamine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	0 (0.0)	1 (5.9)	1 (3.3)
Candesartan	0 (0.0)	1 (5.9)	1 (3.3)
Dihydropyridine Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)
Electrolyte Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Magnesium Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	0 (0.0)	1 (5.9)	1 (3.3)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefazolin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	0 (0.0)	2 (11.8)	2 (6.7)
Dexamethasone Sodium Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Triamcinolone	0 (0.0)	1 (5.9)	1 (3.3)
Opioid Anesthetics	0 (0.0)	1 (5.9)	1 (3.3)
Fentanyl Citrate	0 (0.0)	1 (5.9)	1 (3.3)
Other Opioids	0 (0.0)	1 (5.9)	1 (3.3)
Tramadol Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccines	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccine Conj 13v (Crm197)	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions For Parenteral Nutrition	0 (0.0)	2 (11.8)	2 (6.7)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-6-1-cm-prmed-pop1-sa.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Medication	13 (100.0)	17 (100.0)	30 (100.0)
Serotonin (5ht3) Antagonists	12 (92.3)	15 (88.2)	27 (90.0)
Palonosetron Hydrochloride	5 (38.5)	8 (47.1)	13 (43.3)
Granisetron	3 (23.1)	2 (11.8)	5 (16.7)
Ondansetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Tropisetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Netupitant;palonosetron	1 (7.7)	0 (0.0)	1 (3.3)
Ondansetron	1 (7.7)	5 (29.4)	6 (20.0)
Palonosetron	1 (7.7)	0 (0.0)	1 (3.3)
Tropisetron	1 (7.7)	1 (5.9)	2 (6.7)
Granisetron Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	1 (5.9)	2 (6.7)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-sa.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Sulfonamides, Plain	10 (76.9)	8 (47.1)	18 (60.0)
Furosemide	8 (61.5)	8 (47.1)	16 (53.3)
Torasemide	2 (15.4)	0 (0.0)	2 (6.7)
Indapamide	1 (7.7)	0 (0.0)	1 (3.3)
Osmotically Acting Laxatives	9 (69.2)	8 (47.1)	17 (56.7)
Magnesium Oxide	6 (46.2)	6 (35.3)	12 (40.0)
Lactulose	2 (15.4)	1 (5.9)	3 (10.0)
Macrogol	1 (7.7)	0 (0.0)	1 (3.3)
Magnesium Hydroxide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-sa.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antiemetics	9 (69.2)	13 (76.5)	22 (73.3)
Aprepitant	7 (53.8)	6 (35.3)	13 (43.3)
Fosaprepitant Meglumine	2 (15.4)	8 (47.1)	10 (33.3)
Prochlorperazine	1 (7.7)	1 (5.9)	2 (6.7)
Promethazine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine Hydrochloride;diprophylline	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)
Prochlorperazine Maleate	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Electrolyte Solutions	8 (61.5)	13 (76.5)	21 (70.0)
Potassium Chloride	6 (46.2)	5 (29.4)	11 (36.7)
Magnesium Sulfate	4 (30.8)	8 (47.1)	12 (40.0)
Calcium Chloride;potassium Chloride;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Electrolyte Solutions [umbrella Term]	0 (0.0)	1 (5.9)	1 (3.3)
Potassium	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Phosphate	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Proton Pump Inhibitors	8 (61.5)	12 (70.6)	20 (66.7)
Omeprazole	4 (30.8)	1 (5.9)	5 (16.7)
Esomeprazole Sodium	2 (15.4)	0 (0.0)	2 (6.7)
Lansoprazole	2 (15.4)	2 (11.8)	4 (13.3)
Esomeprazole	1 (7.7)	2 (11.8)	3 (10.0)
Esomeprazole Magnesium	1 (7.7)	0 (0.0)	1 (3.3)
Pantoprazole	1 (7.7)	0 (0.0)	1 (3.3)
Dexlansoprazole	0 (0.0)	1 (5.9)	1 (3.3)
Omeprazole Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Pantoprazole Sodium Sesquihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Rabeprazole Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Vonoprazan Fumarate	0 (0.0)	3 (17.6)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	7 (53.8)	12 (70.6)	19 (63.3)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	3 (17.6)	5 (16.7)
Electrolytes Nos;glucose	2 (15.4)	1 (5.9)	3 (10.0)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	0 (0.0)	2 (6.7)
Sodium Chloride	2 (15.4)	7 (41.2)	9 (30.0)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Gluconate Monohydrate;glucose;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate;sodium Chloride;sodium Citrate Dihydrate	1 (7.7)	1 (5.9)	2 (6.7)
Glucose;sodium Chloride	1 (7.7)	2 (11.8)	3 (10.0)
Solutions Affecting The Electrolyte Balance	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-sa.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Chloride;sodium Lactate	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride;magnesium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;potassium Chloride;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;sodium Chloride;sodium Lactate	0 (0.0)	4 (23.5)	4 (13.3)
H2-Receptor Antagonists	6 (46.2)	2 (11.8)	8 (26.7)
Famotidine	3 (23.1)	1 (5.9)	4 (13.3)
Cimetidine	2 (15.4)	0 (0.0)	2 (6.7)
Lafutidine	1 (7.7)	0 (0.0)	1 (3.3)
Ranitidine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Propulsives	6 (46.2)	6 (35.3)	12 (40.0)
Metoclopramide Dihydrochloride	3 (23.1)	1 (5.9)	4 (13.3)
Domperidone	1 (7.7)	2 (11.8)	3 (10.0)
Metoclopramide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Mosapride Citrate	1 (7.7)	1 (5.9)	2 (6.7)
Alizapride	0 (0.0)	1 (5.9)	1 (3.3)
Antiemetics And Antinauseants	5 (38.5)	10 (58.8)	15 (50.0)
Metoclopramide	4 (30.8)	5 (29.4)	9 (30.0)
Metoclopramide Hydrochloride	1 (7.7)	5 (29.4)	6 (20.0)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Colony Stimulating Factors	5 (38.5)	2 (11.8)	7 (23.3)
Filgrastim	3 (23.1)	1 (5.9)	4 (13.3)
Peg Granulocyte Colony Stimulating Factor	2 (15.4)	0 (0.0)	2 (6.7)
Mecapegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Pegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Granulocyte Colony Stimulating Factor	0 (0.0)	1 (5.9)	1 (3.3)
Solutions Producing Osmotic Diuresis	5 (38.5)	7 (41.2)	12 (40.0)
Mannitol	5 (38.5)	7 (41.2)	12 (40.0)
Anilides	4 (30.8)	9 (52.9)	13 (43.3)
Paracetamol	4 (30.8)	9 (52.9)	13 (43.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Blood Substitutes And Perfusion Solutions	4 (30.8)	4 (23.5)	8 (26.7)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	4 (30.8)	4 (23.5)	8 (26.7)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	4 (30.8)	2 (11.8)	6 (20.0)
Amoxicillin;clavulanic Acid	2 (15.4)	0 (0.0)	2 (6.7)
Amoxicillin Trihydrate;clavulanate Potassium	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Ampicillin Sodium;sulbactam Sodium	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Contact Laxatives	4 (30.8)	8 (47.1)	12 (40.0)
Sennoside A+b	3 (23.1)	6 (35.3)	9 (30.0)
Bisacodyl	1 (7.7)	3 (17.6)	4 (13.3)
Sennoside A+b Calcium	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Picosulfate	1 (7.7)	4 (23.5)	5 (16.7)
Senna Alexandrina Extract	0 (0.0)	1 (5.9)	1 (3.3)
Fluoroquinolones	4 (30.8)	2 (11.8)	6 (20.0)
Levofloxacin	3 (23.1)	1 (5.9)	4 (13.3)
Ciprofloxacin	1 (7.7)	0 (0.0)	1 (3.3)
Ofloxacin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Heparin Group	4 (30.8)	3 (17.6)	7 (23.3)
Heparin Calcium	2 (15.4)	0 (0.0)	2 (6.7)
Bemiparin	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin	0 (0.0)	1 (5.9)	1 (3.3)
Heparin Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Corticosteroids, Potent (Group Iii)	3 (23.1)	1 (5.9)	4 (13.3)
Betamethasone Butyrate Propionate	1 (7.7)	0 (0.0)	1 (3.3)
Halometasone	1 (7.7)	0 (0.0)	1 (3.3)
Mometasone Furoate	1 (7.7)	0 (0.0)	1 (3.3)
Betamethasone Valerate	0 (0.0)	1 (5.9)	1 (3.3)
Difluprednate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Dihydropyridine Derivatives	3 (23.1)	3 (17.6)	6 (20.0)
Cilnidipine	2 (15.4)	0 (0.0)	2 (6.7)
Amlodipine	1 (7.7)	2 (11.8)	3 (10.0)
Lercanidipine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)
Imidazole And Triazole Derivatives	3 (23.1)	1 (5.9)	4 (13.3)
Clobetasol Propionate;ketoconazole	1 (7.7)	0 (0.0)	1 (3.3)
Clotrimazole	1 (7.7)	0 (0.0)	1 (3.3)
Econazole Nitrate	1 (7.7)	0 (0.0)	1 (3.3)
Lanoconazole	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Mucolytics	3 (23.1)	3 (17.6)	6 (20.0)
Acetylcysteine	2 (15.4)	0 (0.0)	2 (6.7)
Ambroxol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Bromhexine Hydrochloride	0 (0.0)	2 (11.8)	2 (6.7)
Carbocisteine	0 (0.0)	1 (5.9)	1 (3.3)
Other Plain Vitamin Preparations	3 (23.1)	1 (5.9)	4 (13.3)
Pyridoxine Hydrochloride	3 (23.1)	1 (5.9)	4 (13.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Potassium	3 (23.1)	2 (11.8)	5 (16.7)
Potassium Chloride	2 (15.4)	0 (0.0)	2 (6.7)
Potassium Aspartate	1 (7.7)	2 (11.8)	3 (10.0)
Potassium Gluconate	0 (0.0)	1 (5.9)	1 (3.3)
Solutions For Parenteral Nutrition	3 (23.1)	6 (35.3)	9 (30.0)
Amino Acids Nos;fats Nos;glucose	2 (15.4)	0 (0.0)	2 (6.7)
Dl-Alpha Tocopheryl Acetate;glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	2 (15.4)	0 (0.0)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetic Acid;alanine;arginine;aspartic Acid;calcium;calcium Chloride;chloride;glucose;glutamate Sodium;glycerol;glycine;glycine Max Seed Oil;histidine;isoleucine;lecithin;leucine;lysine Hydrochloride;magnesium;magnesium Sulfate;methionine;phenylalanine;phosphorus;potassium;potassium Chloride;proline;serine;sodium;sodium Acetate;sodium Glycerophosphate;sodium Hydroxide;threonine;tryptophan, L-;tyrosine;valine	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Glucose	1 (7.7)	2 (11.8)	3 (10.0)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)
Alanine;arginine;aspartic Acid;calcium Chloride;glucose Monohydrate;glutamic Acid;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate;methionine;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	0 (0.0)	2 (11.8)	2 (6.7)
Substituted Alkylamines	3 (23.1)	3 (17.6)	6 (20.0)
Dexchlorpheniramine Maleate	2 (15.4)	2 (11.8)	4 (13.3)
Chlorphenamine	1 (7.7)	0 (0.0)	1 (3.3)
Chlorphenamine Maleate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Unspecified Herbal And Traditional Medicine	3 (23.1)	5 (29.4)	8 (26.7)
Unspecified Herbal And Traditional Medicine	2 (15.4)	0 (0.0)	2 (6.7)
Angelica Sinensis Root;atractylodes Macrocephala, Rhizoma;cremastra Appendiculata Pseudobulb;epimedium Spp.;panax Ginseng Root;solanum Lyratum;sophora Flavescens Root	1 (7.7)	0 (0.0)	1 (3.3)
Animal Unspecified;borneol;cow Bezoar;fungi Nos;indigo;pearl	1 (7.7)	0 (0.0)	1 (3.3)
Angelica Dahurica Root;calcium Sulfate Dihydrate;chrysanthemum X Morifolium Flower;coptis Chinensis Rhizome;forsythia Suspensa Fruit;gardenia Jasminoides Fruit;glycyrrhiza Spp. Root With Rhizome;inula Japonica Inflorescence;ligusticum Chuanxiong Rhizome;mentha Canadensis Herb;phellodendron Chinense Bark;platycodon Grandiflorus Root;rheum Spp. Root With Rhizome;saposhnikovia Divaricata Root;schizonepeta Tenuifolia Spike;scutellaria Baicalensis Root;vitex Trifolia Fruit	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	0 (0.0)	1 (5.9)	1 (3.3)
Citrus Aurantium Pericarp;creosote;glycyrrhiza Spp. Root With Rhizome;phellodendron Spp. Stem Bark;senegalia Catechu Twig	0 (0.0)	1 (5.9)	1 (3.3)
Coptis Spp.;glycyrrhiza Spp.;panax Ginseng;pinellia Ternata;scutellaria Baicalensis;zingiber Officinale;ziziphus Jujuba	0 (0.0)	1 (5.9)	1 (3.3)
Glycine Max Seed Oil	0 (0.0)	1 (5.9)	1 (3.3)
Glycyrrhiza Spp. Root;paeonia Lactiflora Root	0 (0.0)	2 (11.8)	2 (6.7)
Isatis Tinctoria Root;lobelia Chinensis Herb;taraxacum Spp. Herb;viola Philippica Herb	0 (0.0)	1 (5.9)	1 (3.3)
Panax Ginseng Root;zanthoxylum Piperitum Pericarp;zingiber Officinale Processed Rhizome	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antiinfectives And Antiseptics For Local Oral Treatment	2 (15.4)	1 (5.9)	3 (10.0)
Chlorhexidine	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Antiinfectives And Antiseptics For Local Oral Treatment	0 (0.0)	1 (5.9)	1 (3.3)
Ascorbic Acid (Vitamin C), Plain	2 (15.4)	1 (5.9)	3 (10.0)
Ascorbic Acid	2 (15.4)	1 (5.9)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Brotizolam	1 (7.7)	2 (11.8)	3 (10.0)
Estazolam	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Midazolam	1 (7.7)	1 (5.9)	2 (6.7)
Alprazolam	0 (0.0)	3 (17.6)	3 (10.0)
Flunitrazepam	0 (0.0)	1 (5.9)	1 (3.3)
Phenazepam	0 (0.0)	1 (5.9)	1 (3.3)
Biguanides	2 (15.4)	2 (11.8)	4 (13.3)
Metformin	1 (7.7)	0 (0.0)	1 (3.3)
Metformin Hydrochloride	1 (7.7)	2 (11.8)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Vitamins	2 (15.4)	0 (0.0)	2 (6.7)
Combinations Of Vitamins	1 (7.7)	0 (0.0)	1 (3.3)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)
Corticosteroids For Local Oral Treatment	2 (15.4)	2 (11.8)	4 (13.3)
Dexamethasone	2 (15.4)	2 (11.8)	4 (13.3)
Triamcinolone	1 (7.7)	0 (0.0)	1 (3.3)
General Nutrients	2 (15.4)	2 (11.8)	4 (13.3)
General Nutrients	1 (7.7)	2 (11.8)	3 (10.0)
Nutrients Nos	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Insulins And Analogues For Injection, Fast-Acting	2 (15.4)	3 (17.6)	5 (16.7)
Insulin	2 (15.4)	1 (5.9)	3 (10.0)
Insulin Human	0 (0.0)	1 (5.9)	1 (3.3)
Insulin Lispro	0 (0.0)	1 (5.9)	1 (3.3)
Macrolides	2 (15.4)	0 (0.0)	2 (6.7)
Roxithromycin	2 (15.4)	0 (0.0)	2 (6.7)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	2 (15.4)	0 (0.0)	2 (6.7)
Entecavir	2 (15.4)	0 (0.0)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Opium Alkaloids And Derivatives	2 (15.4)	1 (5.9)	3 (10.0)
Dextromethorphan	1 (7.7)	0 (0.0)	1 (3.3)
Dextromethorphan Hydrobromide	1 (7.7)	1 (5.9)	2 (6.7)
Other Antihistamines For Systemic Use	2 (15.4)	1 (5.9)	3 (10.0)
Cyproheptadine	1 (7.7)	0 (0.0)	1 (3.3)
Ebastine	1 (7.7)	0 (0.0)	1 (3.3)
Mebhydrolin	1 (7.7)	0 (0.0)	1 (3.3)
Rupatadine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs For Constipation	2 (15.4)	2 (11.8)	4 (13.3)
Glycerol	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	1 (7.7)	2 (11.8)	3 (10.0)
Linaclotide	0 (0.0)	1 (5.9)	1 (3.3)
Other Immunostimulants	2 (15.4)	1 (5.9)	3 (10.0)
Batilol	1 (7.7)	1 (5.9)	2 (6.7)
Leucogen	1 (7.7)	0 (0.0)	1 (3.3)
Preparations Inhibiting Uric Acid Production	2 (15.4)	3 (17.6)	5 (16.7)
Allopurinol	1 (7.7)	1 (5.9)	2 (6.7)
Febuxostat	1 (7.7)	3 (17.6)	4 (13.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Propionic Acid Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Dexketoprofen	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen	1 (7.7)	1 (5.9)	2 (6.7)
Loxoprofen Sodium	1 (7.7)	3 (17.6)	4 (13.3)
Flurbiprofen Axetil	0 (0.0)	1 (5.9)	1 (3.3)
Loxoprofen Sodium Dihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Zaltoprofen	0 (0.0)	1 (5.9)	1 (3.3)
Acetic Acid Derivatives And Related Substances	1 (7.7)	0 (0.0)	1 (3.3)
Diclofenac Sodium	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	1 (7.7)	0 (0.0)	1 (3.3)
Fluticasone Furoate;vilanterol Trifenatate	1 (7.7)	0 (0.0)	1 (3.3)
Alpha-Adrenoreceptor Antagonists	1 (7.7)	1 (5.9)	2 (6.7)
Silodosin	1 (7.7)	1 (5.9)	2 (6.7)
Amides	1 (7.7)	1 (5.9)	2 (6.7)
Lidocaine	1 (7.7)	0 (0.0)	1 (3.3)
Lidocaine Hydrochloride;prilocaine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Aminoalkyl Ethers	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine	1 (7.7)	0 (0.0)	1 (3.3)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	1 (7.7)	1 (5.9)	2 (6.7)
Cilnidipine;valsartan	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate;telmisartan	0 (0.0)	1 (5.9)	1 (3.3)
Antibacterials For Systemic Use	1 (7.7)	0 (0.0)	1 (3.3)
Antibiotics	1 (7.7)	0 (0.0)	1 (3.3)
Antibiotics	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Rifampicin	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antidotes	1 (7.7)	1 (5.9)	2 (6.7)
Glutathione	1 (7.7)	1 (5.9)	2 (6.7)
Antiinflammatory Preparations, Non-Steroids For Topical Use	1 (7.7)	1 (5.9)	2 (6.7)
Felbinac	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Antipropulsives	1 (7.7)	1 (5.9)	2 (6.7)
Loperamide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Appetite Stimulants	1 (7.7)	0 (0.0)	1 (3.3)
Megestrol	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Related Drugs	1 (7.7)	3 (17.6)	4 (13.3)
Zolpidem	1 (7.7)	0 (0.0)	1 (3.3)
Eszopiclone	0 (0.0)	2 (11.8)	2 (6.7)
Zolpidem Tartrate	0 (0.0)	2 (11.8)	2 (6.7)
Benzomorphan Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Pentazocine	1 (7.7)	0 (0.0)	1 (3.3)
Beta Blocking Agents, Non-Selective	1 (7.7)	0 (0.0)	1 (3.3)
Propranolol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Beta Blocking Agents, Selective	1 (7.7)	2 (11.8)	3 (10.0)
Atenolol	1 (7.7)	0 (0.0)	1 (3.3)
Bisoprolol	1 (7.7)	1 (5.9)	2 (6.7)
Bisoprolol Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Calcium, Combinations With Vitamin D And/Or Other Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Carbonate;colecalciferol;magnesium Carbonate	1 (7.7)	0 (0.0)	1 (3.3)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	1 (7.7)	0 (0.0)	1 (3.3)
Almagate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid;rifampicin	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Various Lipid Modifying Agents	1 (7.7)	0 (0.0)	1 (3.3)
Atorvastatin;ezetimibe	1 (7.7)	0 (0.0)	1 (3.3)
Corticosteroids, Very Potent (Group Iv)	1 (7.7)	1 (5.9)	2 (6.7)
Clobetasol Propionate	1 (7.7)	1 (5.9)	2 (6.7)
Corticosteroids, Weak (Group I)	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Coxibs	1 (7.7)	1 (5.9)	2 (6.7)
Etoricoxib	1 (7.7)	0 (0.0)	1 (3.3)
Celecoxib	0 (0.0)	1 (5.9)	1 (3.3)
Diazepines, Oxazepines, Thiazepines And Oxepines	1 (7.7)	4 (23.5)	5 (16.7)
Quetiapine	1 (7.7)	0 (0.0)	1 (3.3)
Olanzapine	0 (0.0)	4 (23.5)	4 (13.3)
Quetiapine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Enemas	1 (7.7)	0 (0.0)	1 (3.3)
Glycerol	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Enzymes	1 (7.7)	1 (5.9)	2 (6.7)
Bromelains;cysteine	1 (7.7)	0 (0.0)	1 (3.3)
Pronase;sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	1 (7.7)	4 (23.5)	5 (16.7)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	1 (7.7)	2 (11.8)	3 (10.0)
Carbohydrates Nos;electrolytes Nos;lipids Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
Fibrates	1 (7.7)	0 (0.0)	1 (3.3)
Bezafibrate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Heparins Or Heparinoids For Topical Use	1 (7.7)	0 (0.0)	1 (3.3)
Mucopolysaccharide Polysulfuric Acid Ester	1 (7.7)	0 (0.0)	1 (3.3)
Hmg Coa Reductase Inhibitors	1 (7.7)	3 (17.6)	4 (13.3)
Pravastatin	1 (7.7)	1 (5.9)	2 (6.7)
Simvastatin	1 (7.7)	1 (5.9)	2 (6.7)
Rosuvastatin	0 (0.0)	1 (5.9)	1 (3.3)
Hydrazides	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-sa.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	1 (7.7)	1 (5.9)	2 (6.7)
Insulin Human;insulin Human Injection, Isophane	1 (7.7)	0 (0.0)	1 (3.3)
Insulin Aspart;insulin Aspart Protamine (Crystalline)	0 (0.0)	1 (5.9)	1 (3.3)
Leukotriene Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Montelukast	1 (7.7)	0 (0.0)	1 (3.3)
Medical Gases	1 (7.7)	0 (0.0)	1 (3.3)
Oxygen	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-sa.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Natural Opium Alkaloids	1 (7.7)	6 (35.3)	7 (23.3)
Codeine	1 (7.7)	0 (0.0)	1 (3.3)
Codeine Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Hydromorphone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Naloxone Hydrochloride;oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Agents For Local Oral Treatment	1 (7.7)	6 (35.3)	7 (23.3)
Sodium Gualenate Hydrate	1 (7.7)	3 (17.6)	4 (13.3)
Benzydamine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Diclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Glycerol	0 (0.0)	1 (5.9)	1 (3.3)
Lidocaine	0 (0.0)	2 (11.8)	2 (6.7)
Other Analgesics And Antipyretics	1 (7.7)	1 (5.9)	2 (6.7)
Pregabalin	1 (7.7)	1 (5.9)	2 (6.7)
Other Antibiotics For Topical Use	1 (7.7)	2 (11.8)	3 (10.0)
Mupirocin	1 (7.7)	1 (5.9)	2 (6.7)
Gentamicin Sulfate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antidepressants	1 (7.7)	2 (11.8)	3 (10.0)
Mianserin	1 (7.7)	0 (0.0)	1 (3.3)
Trazodone	0 (0.0)	1 (5.9)	1 (3.3)
Trazodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Other Antidiarrheals	1 (7.7)	0 (0.0)	1 (3.3)
Racecadotril	1 (7.7)	0 (0.0)	1 (3.3)
Other Blood Glucose Lowering Drugs, Excl. Insulins	1 (7.7)	0 (0.0)	1 (3.3)
Repaglinide	1 (7.7)	0 (0.0)	1 (3.3)
Other Dermatologicals	1 (7.7)	0 (0.0)	1 (3.3)
Camphor;methyl Salicylate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs Affecting Bone Structure And Mineralization	1 (7.7)	0 (0.0)	1 (3.3)
Denosumab	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	1 (5.9)	2 (6.7)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Simeticone	0 (0.0)	1 (5.9)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	1 (5.9)	2 (6.7)
Sucralfate	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Alginate	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Ethambutol	1 (7.7)	0 (0.0)	1 (3.3)
Pyrazinamide	1 (7.7)	0 (0.0)	1 (3.3)
Other Hypnotics And Sedatives	1 (7.7)	2 (11.8)	3 (10.0)
Doxepin Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Suvorexant	0 (0.0)	2 (11.8)	2 (6.7)
Other Intestinal Adsorbents	1 (7.7)	1 (5.9)	2 (6.7)
Montmorillonite	1 (7.7)	0 (0.0)	1 (3.3)
Gelatin Tannate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Nervous System Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Mecobalamin	1 (7.7)	0 (0.0)	1 (3.3)
Other Throat Preparations	1 (7.7)	0 (0.0)	1 (3.3)
Benzydamine	1 (7.7)	0 (0.0)	1 (3.3)
Other Viral Vaccines	1 (7.7)	2 (11.8)	3 (10.0)
Covid-19 Vaccine Mrna (Mrna 1273)	1 (7.7)	0 (0.0)	1 (3.3)
Tozinameran	0 (0.0)	2 (11.8)	2 (6.7)
Penicillins With Extended Spectrum	1 (7.7)	1 (5.9)	2 (6.7)
Amoxicillin	1 (7.7)	0 (0.0)	1 (3.3)
Amoxicillin Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Phenothiazines With Aliphatic Side-Chain	1 (7.7)	3 (17.6)	4 (13.3)
Chlorpromazine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Chlorpromazine	0 (0.0)	2 (11.8)	2 (6.7)
Piperazine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Levocetirizine	1 (7.7)	0 (0.0)	1 (3.3)
Platelet Aggregation Inhibitors Excl. Heparin	1 (7.7)	2 (11.8)	3 (10.0)
Acetylsalicylate Lysine	1 (7.7)	1 (5.9)	2 (6.7)
Acetylsalicylic Acid	0 (0.0)	1 (5.9)	1 (3.3)
Pyrazolones	1 (7.7)	0 (0.0)	1 (3.3)
Metamizole	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Second-Generation Cephalosporins	1 (7.7)	1 (5.9)	2 (6.7)
Cefaclor	1 (7.7)	0 (0.0)	1 (3.3)
Cefuroxime	0 (0.0)	1 (5.9)	1 (3.3)
Selective Beta-2-Adrenoreceptor Agonists	1 (7.7)	1 (5.9)	2 (6.7)
Bambuterol	1 (7.7)	0 (0.0)	1 (3.3)
Tulobuterol	0 (0.0)	1 (5.9)	1 (3.3)
Selective Serotonin Reuptake Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Sertraline	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Third-Generation Cephalosporins	1 (7.7)	2 (11.8)	3 (10.0)
Ceftriaxone Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Cefcapene Pivoxil Hydrochloride Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Cefoperazone	0 (0.0)	1 (5.9)	1 (3.3)
Tonics	1 (7.7)	0 (0.0)	1 (3.3)
Inosine;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Vitamins	1 (7.7)	1 (5.9)	2 (6.7)
Ascorbic Acid;biotin;cocarboxylase Tetrahydrate;colecalciferol;cyanocobalamin;dexpanthenol;dl-Alpha Tocopherol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)
Ace Inhibitors, Plain	0 (0.0)	2 (11.8)	2 (6.7)
Perindopril	0 (0.0)	2 (11.8)	2 (6.7)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids	0 (0.0)	1 (5.9)	1 (3.3)
Fenoterol Hydrobromide;ipratropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Aldose Reductase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Epalrestat	0 (0.0)	1 (5.9)	1 (3.3)
Aldosterone Antagonists	0 (0.0)	2 (11.8)	2 (6.7)
Spironolactone	0 (0.0)	2 (11.8)	2 (6.7)
Alpha Glucosidase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Voglibose	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids And Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Ademetionine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antidiarrheal Microorganisms	0 (0.0)	3 (17.6)	3 (10.0)
Antidiarrheal Microorganisms	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Subtilis;lactomin	0 (0.0)	1 (5.9)	1 (3.3)
Antiseptics	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate;sodium Gualenate Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	0 (0.0)	1 (5.9)	1 (3.3)
Cimetropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)
Benzamides	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Beta Blocking Agents	0 (0.0)	1 (5.9)	1 (3.3)
Timolol	0 (0.0)	1 (5.9)	1 (3.3)
Bioflavonoids	0 (0.0)	1 (5.9)	1 (3.3)
Diosmin;hesperidin	0 (0.0)	1 (5.9)	1 (3.3)
Bisphosphonates	0 (0.0)	1 (5.9)	1 (3.3)
Zoledronic Acid	0 (0.0)	1 (5.9)	1 (3.3)
Butyrophenone Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Haloperidol	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Carbamide Products	0 (0.0)	1 (5.9)	1 (3.3)
Urea	0 (0.0)	1 (5.9)	1 (3.3)
Carbapenems	0 (0.0)	2 (11.8)	2 (6.7)
Meropenem	0 (0.0)	1 (5.9)	1 (3.3)
Meropenem Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Combinations Of Oral Blood Glucose Lowering Drugs	0 (0.0)	1 (5.9)	1 (3.3)
Metformin Hydrochloride;sitagliptin Phosphate Monohydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	0 (0.0)	4 (23.5)	4 (13.3)
Linagliptin	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate Monohydrate	0 (0.0)	2 (11.8)	2 (6.7)
Diphenylmethane Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)
Direct Factor Xa Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Apixaban	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefradine	0 (0.0)	1 (5.9)	1 (3.3)
Insulins And Analogues For Injection, Long-Acting	0 (0.0)	1 (5.9)	1 (3.3)
Insulin Glargine Biosimilar 1	0 (0.0)	1 (5.9)	1 (3.3)
Iron Trivalent, Oral Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Ferric Pyrophosphate	0 (0.0)	1 (5.9)	1 (3.3)
Iron, Parenteral Preparations	0 (0.0)	2 (11.8)	2 (6.7)
Saccharated Iron Oxide	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Liver Therapy	0 (0.0)	2 (11.8)	2 (6.7)
Cysteine Hydrochloride;glycine;glycyrrhizic Acid, Ammonium Salt	0 (0.0)	1 (5.9)	1 (3.3)
Ornithine Aspartate	0 (0.0)	1 (5.9)	1 (3.3)
Polyene Phosphatidylcholine	0 (0.0)	1 (5.9)	1 (3.3)
Melatonin Receptor Agonists	0 (0.0)	1 (5.9)	1 (3.3)
Ramelteon	0 (0.0)	1 (5.9)	1 (3.3)
Other Aminoglycosides	0 (0.0)	1 (5.9)	1 (3.3)
Amikacin	0 (0.0)	1 (5.9)	1 (3.3)
Other Antianemic Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Darbepoetin Alfa	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antibacterials	0 (0.0)	1 (5.9)	1 (3.3)
Fosfomycin	0 (0.0)	1 (5.9)	1 (3.3)
Other Antiepileptics	0 (0.0)	1 (5.9)	1 (3.3)
Lacosamide	0 (0.0)	1 (5.9)	1 (3.3)
Levetiracetam	0 (0.0)	1 (5.9)	1 (3.3)
Other Antimigraine Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Flunarizine Dihydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Other Antipruritics	0 (0.0)	1 (5.9)	1 (3.3)
Crotamiton	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Blood Products	0 (0.0)	1 (5.9)	1 (3.3)
Blood, Whole	0 (0.0)	1 (5.9)	1 (3.3)
Other Centrally Acting Agents	0 (0.0)	1 (5.9)	1 (3.3)
Baclofen	0 (0.0)	1 (5.9)	1 (3.3)
Other Emollients And Protectives	0 (0.0)	2 (11.8)	2 (6.7)
Mucopolysaccharide Polysulfuric Acid Ester	0 (0.0)	2 (11.8)	2 (6.7)
Other Irrigating Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Mannitol;sorbitol	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Peripheral Opioid Receptor Antagonists	0 (0.0)	1 (5.9)	1 (3.3)
Naldemedine Tosilate	0 (0.0)	1 (5.9)	1 (3.3)
Phenylpiperidine Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Fentanyl Citrate	0 (0.0)	2 (11.8)	2 (6.7)
Preparations Increasing Uric Acid Excretion	0 (0.0)	1 (5.9)	1 (3.3)
Benzbromarone	0 (0.0)	1 (5.9)	1 (3.3)
Preparations With No Effect On Uric Acid Metabolism	0 (0.0)	1 (5.9)	1 (3.3)
Colchicine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Proteinase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Camostat Mesilate	0 (0.0)	1 (5.9)	1 (3.3)
Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic (Monohydrate)	0 (0.0)	1 (5.9)	1 (3.3)
Soft Paraffin And Fat Products	0 (0.0)	1 (5.9)	1 (3.3)
White Soft Paraffin	0 (0.0)	1 (5.9)	1 (3.3)
Stomatological Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Sulfonylureas	0 (0.0)	1 (5.9)	1 (3.3)
Gliclazide	0 (0.0)	1 (5.9)	1 (3.3)
Triazole Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Fluconazole	0 (0.0)	1 (5.9)	1 (3.3)
Various Alimentary Tract And Metabolism Products	0 (0.0)	2 (11.8)	2 (6.7)
Borneol;cow Bezoar;musk;pearl;potassium Nitrate;realgar;sodium Borate Decahydrate;zingiber Officinale Rhizome	0 (0.0)	1 (5.9)	1 (3.3)
Zinc Acetate	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Disulfide	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Vitamin B12 (Cyanocobalamin And Analogues)	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin B12 Nos	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D And Analogues	0 (0.0)	2 (11.8)	2 (6.7)
Colecalciferol	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D Nos	0 (0.0)	1 (5.9)	1 (3.3)
Xanthines	0 (0.0)	1 (5.9)	1 (3.3)
Theophylline	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Systemically Administered Corticosteroids/Immunosuppressive Drug During the Study	10 (76.9)	14 (82.4)	24 (80.0)
Patients with at Least One Concomitant Systemically Administered Corticosteroids Drugs	10 (76.9)	14 (82.4)	24 (80.0)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	1 (5.9)	2 (6.7)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm1.sas 21OCT2024 08:30 t-14-1-7-2-cm1-cor-pop1-sa.rtf

Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Immunosuppressive Drugs	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm1.sas 21OCT2024 08:30 t-14-1-7-2-cm1-cor-pop1-sa.rtf

Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Overall Survival [a]			
n	13	17	30
Mean (SD)	26.59 (13.024)	16.21 (13.398)	20.71 (14.021)
Median	26.48	9.76	19.83
Q1, Q3	19.12, 37.88	6.97, 23.82	7.98, 32.59
Min, Max	1.8, 44.0	2.2, 43.7	1.8, 44.0
Progression-Free Survival [b]			
n	13	17	30
Mean (SD)	14.33 (15.713)	8.50 (11.013)	11.03 (13.331)
Median	5.68	4.44	5.52
Q1, Q3	2.83, 29.08	2.07, 8.54	2.76, 9.95
Min, Max	1.8, 42.3	1.2, 42.1	1.2, 42.3

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Investigator Tumor Assessment [c]			
n	13	17	30
Mean (SD)	14.38 (15.678)	8.64 (10.945)	11.13 (13.273)
Median	5.68	4.44	5.60
Q1, Q3	4.04, 29.08	2.66, 8.54	2.76, 9.95
Min, Max	1.3, 42.3	1.2, 42.1	1.2, 42.3
EORTC-QLQ-C30 [d]			
n	13	17	30
Mean (SD)	8.56 (9.092)	7.58 (8.173)	8.01 (8.444)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 27.4	1.0, 29.9	0.0, 29.9

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-sum-eff.sas 21OCT2024 08:38 t-14-1-8-1-sum-eff-pop1-sa.rtf

Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
EORTC-QLQ-OES18 [d]			
n	13	17	30
Mean (SD)	8.56 (9.092)	7.58 (8.173)	8.01 (8.444)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 27.4	1.0, 29.9	0.0, 29.9
EQ-5D VAS [d]			
n	13	17	30
Mean (SD)	8.76 (9.539)	7.58 (8.173)	8.09 (8.652)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 29.9	1.0, 29.9	0.0, 29.9

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.2:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Safety for TEAEs [a]			
n	13	17	30
Mean (SD)	12.86 (13.976)	8.12 (9.018)	10.18 (11.463)
Median	5.98	4.63	5.52
Q1, Q3	2.99, 24.44	2.17, 8.80	2.83, 10.28
Min, Max	1.2, 44.0	1.2, 32.9	1.2, 44.0
Safety for imAEs [b]			
n	13	17	30
Mean (SD)	14.67 (13.663)	9.80 (9.227)	11.91 (11.412)
Median	7.95	6.60	7.31
Q1, Q3	5.22, 26.41	3.94, 11.53	4.17, 12.71
Min, Max	1.8, 44.0	2.1, 34.9	1.8, 44.0

Source: ADSL, ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event; imAE, immune-mediated adverse event.

[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.

[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Number of Patients		
Death, n (%)	7 (53.8)	11 (64.7)
Censored, n (%)	6 (46.2)	6 (35.3)
Ongoing Without Events	6 (46.2)	4 (23.5)
Lost to Follow-up	0 (0.0)	1 (5.9)
Withdrawal by Subject	0 (0.0)	1 (5.9)
Two-sided Stratified Log-rank Test p-value [a]	0.4086	
Stratified Hazard Ratio (95% CI) [b]	0.611 (0.189, 1.975)	
Unstratified Hazard Ratio (95% CI) [c]	0.537 (0.206, 1.398)	

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Overall Survival (months)		
Median (95% CI)	26.5 (16.4, NE)	11.8 (7.0, NE)
Q1 (95% CI)	19.1 (1.8, 26.5)	8.0 (2.2, 11.8)
Q3 (95% CI)	NR (26.0, NE)	NR (11.8, NE)

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	92.3 (56.6, 98.9)	88.2 (60.6, 96.9)
6 Months (95% CI)	92.3 (56.6, 98.9)	82.4 (54.7, 93.9)
9 Months (95% CI)	84.6 (51.2, 95.9)	69.1 (40.7, 85.9)
12 Months (95% CI)	84.6 (51.2, 95.9)	48.4 (22.5, 70.2)
18 Months (95% CI)	76.9 (44.2, 91.9)	48.4 (22.5, 70.2)
24 Months (95% CI)	61.5 (30.8, 81.8)	27.6 (8.7, 50.9)
30 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)
36 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)
42 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
48 Months (95% CI)	NR (NE, NE)	NR (NE, NE)
Follow-up Time (months)		
Median (95% CI)	38.5 (31.6, NE)	32.6 (31.1, NE)

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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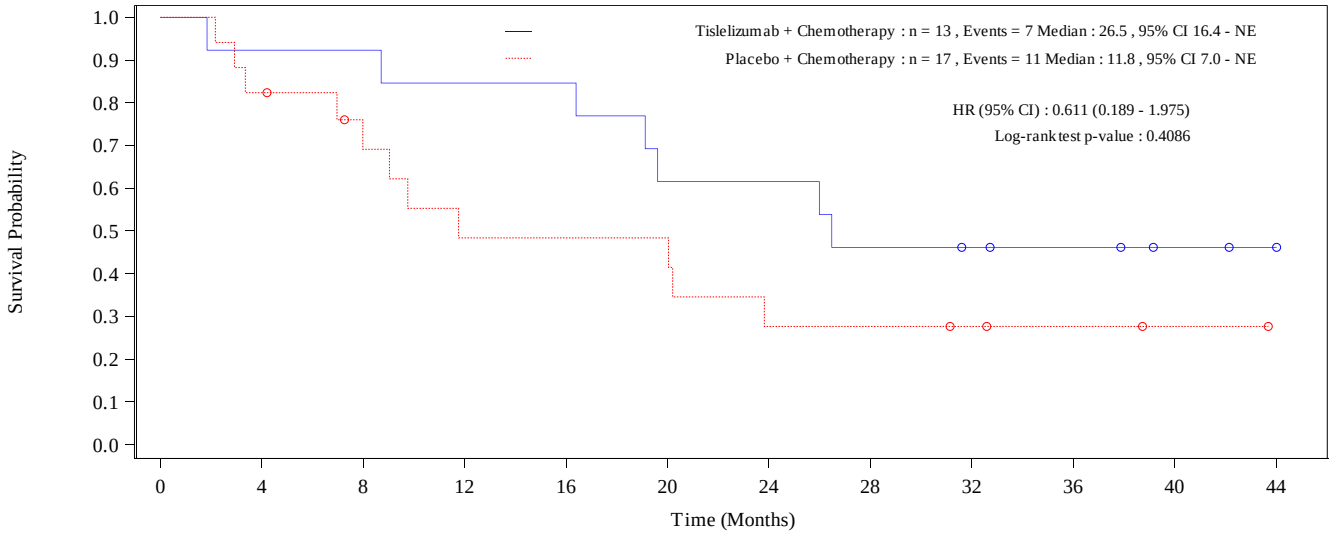
Figure 14.2.1.1:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
Tislelizumab +Chemotherapy	13	13	12	12	12	12	12	12	12	11	11	11	11	11	11	11	11	10	10	10	8	8	8	8	8	8	7	6	6	6	6	6	5	4	4	4	4	4	3	3	2	2	2	1	1	0
Placebo +Chemotherapy	17	17	17	15	14	13	13	12	10	10	8	8	7	7	7	7	7	7	7	7	5	5	5	4	4	4	4	4	4	4	4	3	2	2	2	2	2	2	1	1	1	1	1	0	0	

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE, not estimable; NR, not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy. (yes vs no) per IRT.
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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	4 (44.4)	NR (8.7, NE)	8	4 (50.0)	20.0 (3.4, NE)	0.531 (0.131, 2.147)	0.3668
Age >= 65	4	3 (75.0)	26.2 (1.8, NE)	9	7 (77.8)	9.8 (2.2, NE)	0.666 (0.167, 2.663)	0.5631
Interaction								0.8228
Sex								
Male	9	6 (66.7)	26.0 (1.8, NE)	11	7 (63.6)	20.0 (2.9, NE)	0.794 (0.265, 2.380)	0.6798
Female	4	1 (25.0)	NR (19.1, NE)	6	4 (66.7)	9.8 (7.0, NE)	0.192 (0.021, 1.750)	0.1043
Interaction								0.2652

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	19.6 (8.7, 26.5)	10	7 (70.0)	9.8 (2.9, NE)	0.731 (0.243, 2.199)	0.5756
1	6	1 (16.7)	NR (1.8, NE)	7	4 (57.1)	20.2 (2.2, NE)	0.240 (0.026, 2.186)	0.1708
Interaction								0.2303

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	NR (8.7, NE)	7	5 (71.4)	9.8 (2.2, NE)	0.559 (0.108, 2.899)	0.4828
No	9	5 (55.6)	26.5 (1.8, NE)	10	6 (60.0)	20.0 (2.9, NE)	0.535 (0.159, 1.792)	0.3033
Interaction								0.9954

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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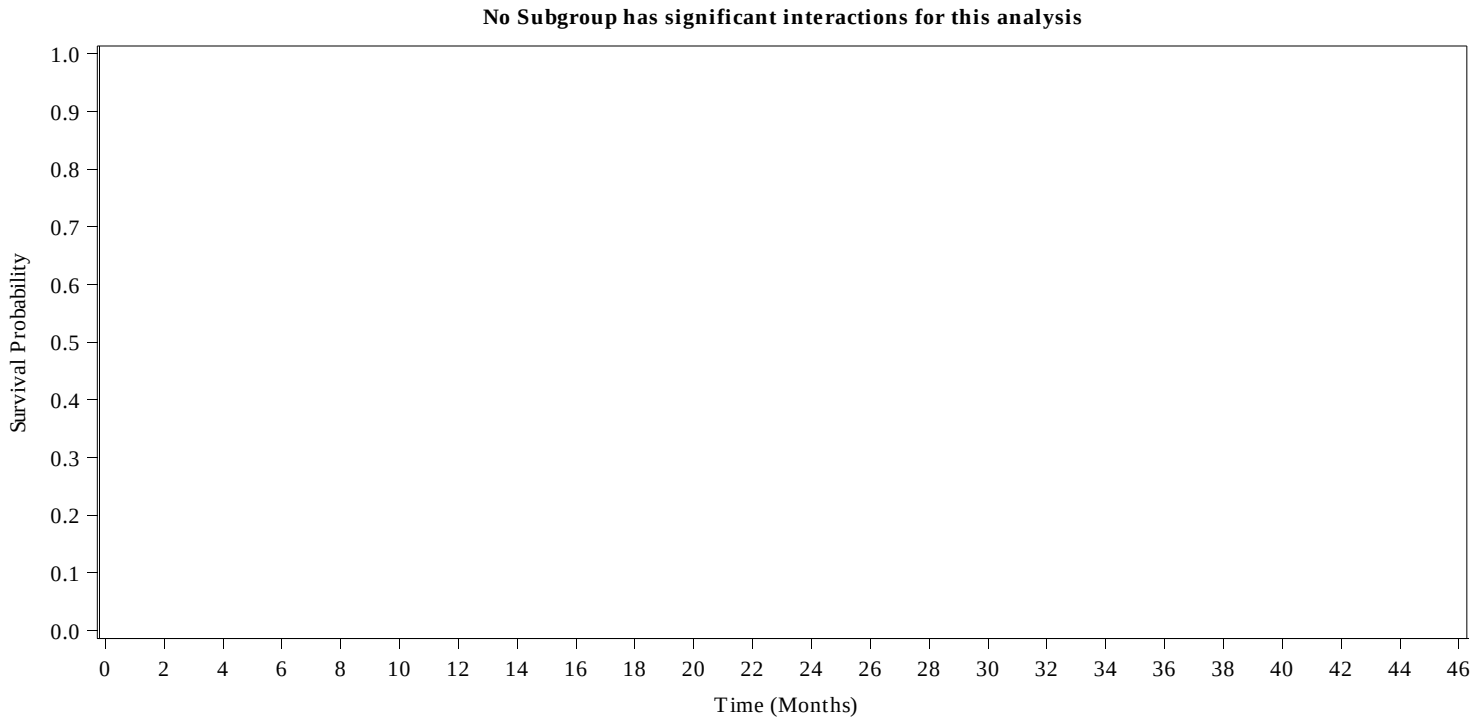
Figure 14.2.1.1.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression-Free Survival		
Events, n (%)	9 (69.2)	14 (82.4)
Progressive Disease	8 (61.5)	14 (82.4)
Death	1 (7.7)	0 (0.0)
Censored, n (%)	4 (30.8)	3 (17.6)
New Anti-Cancer Therapy	1 (7.7)	1 (5.9)
No PD/Death [a]	3 (23.1)	2 (11.8)
Ongoing Without Events	3 (23.1)	2 (11.8)
Two-sided Stratified Log-rank Test p-value [b]	0.2759	
Stratified Hazard Ratio (95% CI) [c]	0.580 (0.216, 1.557)	
Unstratified Hazard Ratio (95% CI) [d]	0.608 (0.260, 1.420)	

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression Free Survival (months)		
Median (95% CI)	6.9 (2.8, NE)	4.4 (1.3, 8.5)
Q1 (95% CI)	5.6 (1.8, 5.7)	2.1 (1.2, 4.1)
Q3 (95% CI)	NR (5.7, NE)	8.5 (4.4, NE)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	76.9 (44.2, 91.9)	58.8 (32.5, 77.8)
6 Months (95% CI)	51.3 (21.9, 74.6)	35.3 (14.5, 57.0)
9 Months (95% CI)	34.2 (10.7, 59.8)	23.5 (7.3, 44.9)
12 Months (95% CI)	34.2 (10.7, 59.8)	17.6 (4.3, 38.3)

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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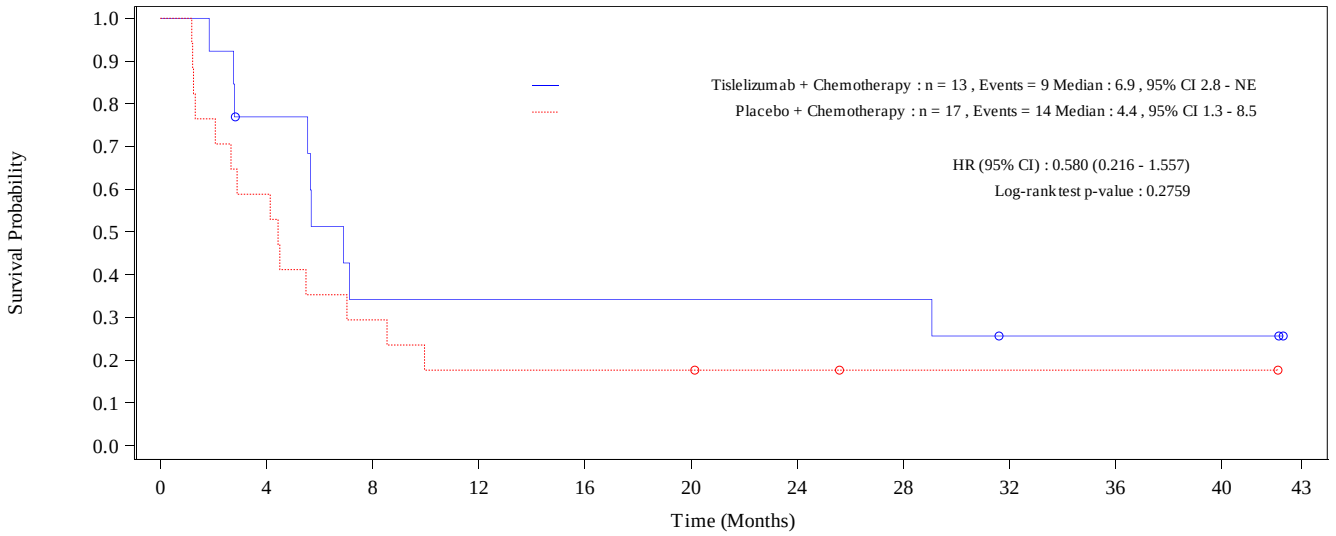
Figure 14.2.4.1:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
Tislelizumab +Chemotherapy	13	13	12	9	9	9	6	5	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	3	2	2	2	2	2	2	2	2	2	2	2	2	0
Placebo +Chemotherapy	17	17	13	10	10	7	6	6	5	4	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE, not estimable.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	6 (66.7)	5.7 (2.8, NE)	8	6 (75.0)	3.5 (1.2, NE)	0.525 (0.159, 1.730)	0.2813
Age >= 65	4	3 (75.0)	6.9 (1.8, NE)	9	8 (88.9)	4.5 (1.2, 10.0)	1.095 (0.272, 4.409)	0.8987
Interaction								0.5314
Sex								
Male	9	7 (77.8)	5.7 (1.8, 7.1)	11	9 (81.8)	4.1 (1.2, 10.0)	1.032 (0.376, 2.836)	0.9514
Female	4	2 (50.0)	NR (2.8, NE)	6	5 (83.3)	4.5 (1.2, NE)	0.213 (0.025, 1.842)	0.1226
Interaction								0.1955

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	5.7 (2.8, NE)	10	9 (90.0)	4.5 (1.3, 7.0)	0.988 (0.338, 2.886)	0.9824
1	6	3 (50.0)	NR (1.8, NE)	7	5 (71.4)	2.9 (1.2, NE)	0.414 (0.096, 1.794)	0.2254
Interaction								0.2934

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	5.7 (2.8, NE)	7	5 (71.4)	4.5 (1.2, NE)	0.547 (0.105, 2.850)	0.4677
No	9	7 (77.8)	6.9 (1.8, NE)	10	9 (90.0)	4.3 (1.2, 8.5)	0.562 (0.199, 1.585)	0.2695
Interaction								0.9647

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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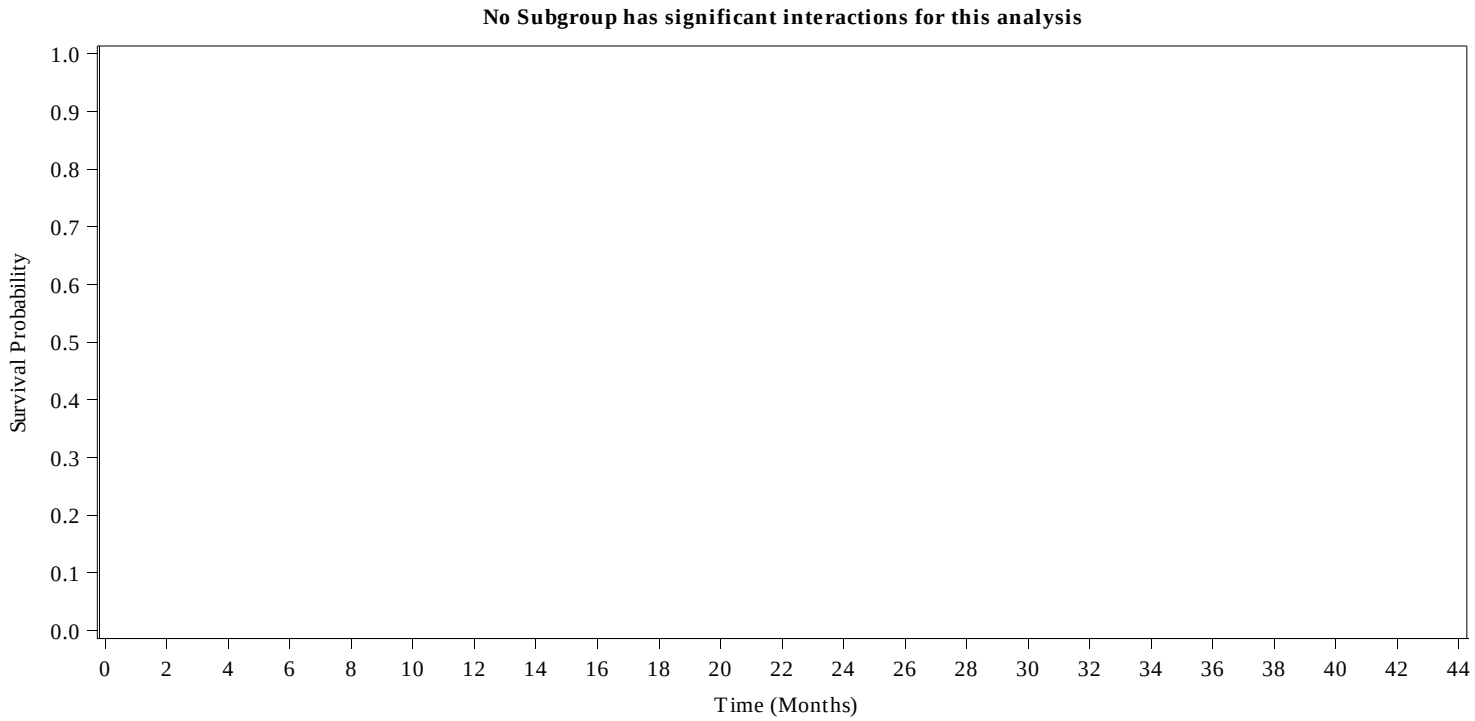
Figure 14.2.4.1.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.2.4.1:
Objective Response
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	11	8				
%	84.6	47.1	5.133 (0.675, 39.019)	1.477 (0.952, 2.292)	27.000 (-5.071, 59.071)	0.1117
Best Overall Response (BOR), n (%)						
Complete Response (CR)	2 (15.4)	1 (5.9)				
Partial Response (PR)	9 (69.2)	7 (41.2)				
Stable Disease (SD) [e]	2 (15.4)	5 (29.4)				
Progressive Disease (PD)	0 (0.0)	4 (23.5)				
Not Evaluable (NE) [c]	0 (0.0)	0 (0.0)				
Not Assessable [d]	0 (0.0)	0 (0.0)				
Disease Control Rate (DCR), n	13	13				
%	100.0	76.5	NE (NE, NE)	1.292 (0.981, 1.702)	22.600 (0.459, 44.741)	0.0975

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE, not estimable.

Percentages were based on N. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[c] Not evaluable is based on RECIST v1.1.

[d] Patients with no post-baseline tumor assessment by the data cutoff, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.

[e] SD includes SD and non-CR/non-PD.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Age								
Age < 65	9	7 (77.8)	8	3 (37.5)	5.833 (0.696, 48.873)	2.074 (0.794, 5.419)	40.278 (-2.887, 83.442)	0.1023
Age >= 65	4	4 (100.0)	9	5 (55.6)	NE (NE, NE)	1.800 (1.003, 3.229)	44.444 (11.981, 76.908)	0.1237
Interaction								0.4682
Sex								
Male	9	8 (88.9)	11	5 (45.5)	9.600 (0.876, 105.166)	1.956 (0.983, 3.888)	43.434 (7.554, 79.315)	0.0483
Female	4	3 (75.0)	6	3 (50.0)	3.000 (0.188, 47.963)	1.500 (0.563, 3.997)	25.000 (-33.321, 83.321)	0.4533
Interaction								0.5300

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
ECOG Performance Score								
0	7	5 (71.4)	10	5 (50.0)	2.500 (0.320, 19.529)	1.429 (0.657, 3.107)	21.429 (-24.182, 67.039)	0.3914
1	6	6 (100.0)	7	3 (42.9)	NE (NE, NE)	2.333 (0.992, 5.489)	57.143 (20.483, 93.803)	0.0325
Interaction								0.1711
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	7	2 (28.6)	7.500 (0.458, 122.696)	2.625 (0.715, 9.640)	46.429 (-7.614, 100.000)	0.1561
No	9	8 (88.9)	10	6 (60.0)	5.333 (0.468, 60.797)	1.481 (0.849, 2.584)	28.889 (-7.765, 65.543)	0.1646
Interaction								0.8566

Source: ADSL, ADTTE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-orr-subgrp.sas 21OCT2024 08:54 t-14-2-4-1-s-eff-orr-subgrp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	66.7
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	50.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	50.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	50.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
End of Treatment		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	9	14
Completion rate (%) [a]	69.2	82.4
Adjusted completion rate (%) [b]	81.8	87.5

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	11
Completion rate (%) [a]	84.6	64.7
Adjusted completion rate (%) [b]	100.0	91.7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	66.7
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	50.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	50.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	50.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
End of Treatment		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	9	14
Completion rate (%) [a]	69.2	82.4
Adjusted completion rate (%) [b]	81.8	87.5

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	8	9
Completion rate (%) [a]	61.5	52.9
Adjusted completion rate (%) [b]	88.9	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	50.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	50.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	66.7	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	50.0	100.0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
End of Treatment		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	9	14
Completion rate (%) [a]	69.2	82.4
Adjusted completion rate (%) [b]	81.8	87.5

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	63.2 (29.83)		57.8 (25.08)	
	Median	83.3		50.0	
	Q1, Q3	37.5, 83.3		50.0, 75.0	
	Min, Max	0, 83		8, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	74.2 (16.87)	10.8 (26.95)	62.2 (20.14)	5.6 (20.33)
	Median	83.3	4.2	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 8.3	50.0, 83.3	-8.3, 25.0
	Min, Max	33, 92	-17, 67	25, 83	-42, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	75.8 (12.08)	12.5 (28.40)	62.5 (26.94)	5.6 (20.21)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 33.3	58.3, 75.0	0.0, 16.7
	Min, Max	58, 92	-25, 67	8, 100	-33, 50

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	77.8 (13.82)	16.7 (23.57)	60.4 (27.55)	3.5 (26.93)
	Median	83.3	8.3	75.0	4.2
	Q1, Q3	66.7, 83.3	0.0, 41.7	41.7, 79.2	-16.7, 20.8
	Min, Max	50, 92	-8, 50	8, 83	-42, 42
Cycle 5	n	8	8	11	11
	Mean (SD)	78.1 (17.78)	12.5 (19.42)	64.4 (26.38)	3.0 (28.69)
	Median	83.3	4.2	66.7	16.7
	Q1, Q3	70.8, 87.5	0.0, 29.2	41.7, 83.3	-25.0, 16.7
	Min, Max	42, 100	-8, 42	17, 100	-42, 42
Cycle 6	n	7	7	9	9
	Mean (SD)	81.0 (11.50)	6.0 (15.75)	71.3 (24.69)	7.4 (28.09)
	Median	83.3	0.0	83.3	0.0
	Q1, Q3	66.7, 83.3	0.0, 16.7	66.7, 83.3	-8.3, 33.3
	Min, Max	67, 100	-17, 33	17, 100	-33, 50

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	81.0 (15.00)	17.9 (22.79)	85.7 (11.50)	17.9 (26.97)
	Median	83.3	8.3	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 100.0	0.0, 41.7
	Min, Max	50, 100	0, 50	67, 100	-8, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (27.22)	16.7 (23.57)	75.0 (29.34)	6.9 (36.29)
	Median	66.7	25.0	83.3	4.2
	Q1, Q3	50.0, 83.3	0.0, 33.3	83.3, 83.3	-8.3, 41.7
	Min, Max	33, 100	-17, 33	17, 100	-50, 50
Cycle 12	n	3	3	5	5
	Mean (SD)	75.0 (14.43)	36.1 (42.76)	70.0 (21.73)	8.3 (31.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	58.3, 83.3	0.0, 83.3	66.7, 83.3	-8.3, 25.0
	Min, Max	58, 83	0, 83	33, 83	-33, 50

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	80.6 (12.73)	41.7 (30.05)	75.0 (8.33)	16.7 (22.05)
	Median	83.3	50.0	75.0	8.3
	Q1, Q3	66.7, 91.7	8.3, 66.7	66.7, 83.3	0.0, 41.7
	Min, Max	67, 92	8, 67	67, 83	0, 42
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	38.9 (25.46)	66.7 (23.57)	-12.5 (5.89)
	Median	66.7	33.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	16.7, 66.7	50.0, 83.3	-16.7, -8.3
	Min, Max	67, 100	17, 67	50, 83	-17, -8
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (34.69)	16.7 (16.67)	72.2 (19.25)	-5.6 (12.73)
	Median	66.7	16.7	83.3	-8.3
	Q1, Q3	16.7, 83.3	0.0, 33.3	50.0, 83.3	-16.7, 8.3
	Min, Max	17, 83	0, 33	50, 83	-17, 8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	72.2 (19.25)	33.3 (28.87)	80.6 (4.81)	2.8 (9.62)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 83.3	0.0, 50.0	75.0, 83.3	-8.3, 8.3
	Min, Max	50, 83	0, 50	75, 83	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (25.46)	38.9 (19.25)	77.8 (9.62)	0.0 (22.05)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 100.0	16.7, 50.0	66.7, 83.3	-25.0, 16.7
	Min, Max	50, 100	17, 50	67, 83	-25, 17
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	83.3 (0.00)	5.6 (12.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 83.3	-8.3, 16.7
	Min, Max	83, 83	0, 50	83, 83	-8, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	83.3 (0.00)	0.0 (11.79)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 83.3	-8.3, 8.3
	Min, Max	83, 83	0, 50	83, 83	-8, 8
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	25.0 (11.79)	83.3 (NE)	-8.3 (NE)
	Median	83.3	25.0	83.3	-8.3
	Q1, Q3	66.7, 100.0	16.7, 33.3	83.3, 83.3	-8.3, -8.3
	Min, Max	67, 100	17, 33	83, 83	-8, -8
Cycle 30	n	2	2	1	1
	Mean (SD)	66.7 (23.57)	50.0 (0.00)	83.3 (NE)	-8.3 (NE)
	Median	66.7	50.0	83.3	-8.3
	Q1, Q3	50.0, 83.3	50.0, 50.0	83.3, 83.3	-8.3, -8.3
	Min, Max	50, 83	50, 50	83, 83	-8, -8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	33.3 (0.00)	83.3 (NE)	-8.3 (NE)
	Median	50.0	33.3	83.3	-8.3
	Q1, Q3	33.3, 66.7	33.3, 33.3	83.3, 83.3	-8.3, -8.3
	Min, Max	33, 67	33, 33	83, 83	-8, -8
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	33.3 (0.00)	75.0 (NE)	-16.7 (NE)
	Median	50.0	33.3	75.0	-16.7
	Q1, Q3	33.3, 66.7	33.3, 33.3	75.0, 75.0	-16.7, -16.7
	Min, Max	33, 67	33, 33	75, 75	-17, -17
Cycle 36	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-8.3 (NE)
	Median			83.3	-8.3
	Q1, Q3			83.3, 83.3	-8.3, -8.3
	Min, Max			83, 83	-8, -8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			91.7 (NE)	0.0 (NE)
	Median			91.7	0.0
	Q1, Q3			91.7, 91.7	0.0, 0.0
	Min, Max			92, 92	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
End of Treatment	n	9	9	14	14
	Mean (SD)	72.2 (9.32)	1.9 (26.93)	58.3 (26.95)	3.0 (23.25)
	Median	66.7	-8.3	66.7	0.0
	Q1, Q3	66.7, 83.3	-16.7, 0.0	33.3, 75.0	-8.3, 8.3
	Min, Max	58, 83	-25, 58	0, 100	-50, 42

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	56.9 (22.14)	-6.3 (13.35)	44.1 (23.89)	-13.7 (21.84)
	Median	66.7	-8.3	50.0	-8.3
	Q1, Q3	45.8, 66.7	-16.7, 0.0	33.3, 66.7	-25.0, 0.0
	Min, Max	17, 83	-25, 17	0, 75	-50, 25

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.7 (21.84)		87.1 (14.23)	
	Median	100.0		86.7	
	Q1, Q3	70.0, 100.0		86.7, 93.3	
	Min, Max	47, 100		47, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	87.3 (18.18)	2.0 (11.78)	77.3 (22.65)	-8.9 (13.25)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 93.3	-13.3, 0.0
	Min, Max	53, 100	-20, 27	20, 100	-40, 13
Cycle 3	n	10	10	12	12
	Mean (SD)	88.0 (19.58)	2.7 (10.04)	73.9 (21.36)	-14.4 (11.66)
	Median	100.0	0.0	80.0	-10.0
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 86.7	-26.7, -6.7
	Min, Max	47, 100	-7, 27	20, 100	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.9 (23.67)	2.2 (14.53)	75.6 (23.33)	-12.8 (12.86)
	Median	100.0	0.0	80.0	-13.3
	Q1, Q3	86.7, 100.0	0.0, 0.0	66.7, 93.3	-23.3, 0.0
	Min, Max	33, 100	-20, 33	13, 100	-33, 7
Cycle 5	n	8	8	11	11
	Mean (SD)	86.7 (24.43)	-0.8 (10.95)	82.4 (15.57)	-9.7 (13.78)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	-3.3, 0.0	66.7, 100.0	-26.7, 0.0
	Min, Max	33, 100	-20, 20	60, 100	-27, 13
Cycle 6	n	7	7	9	9
	Mean (SD)	94.3 (15.12)	1.9 (5.04)	83.7 (12.96)	-8.9 (11.55)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	100.0, 100.0	0.0, 0.0	80.0, 93.3	-13.3, 0.0
	Min, Max	60, 100	0, 13	60, 100	-27, 7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	82.9 (27.72)	-2.9 (8.48)	89.5 (12.68)	-4.8 (10.69)
	Median	100.0	0.0	93.3	0.0
	Q1, Q3	53.3, 100.0	-6.7, 0.0	80.0, 100.0	-6.7, 0.0
	Min, Max	33, 100	-20, 7	67, 100	-27, 7
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (35.69)	-8.3 (8.39)	86.7 (26.67)	-6.7 (26.67)
	Median	70.0	-6.7	100.0	0.0
	Q1, Q3	36.7, 96.7	-13.3, -3.3	86.7, 100.0	0.0, 6.7
	Min, Max	27, 100	-20, 0	33, 100	-60, 13
Cycle 12	n	3	3	5	5
	Mean (SD)	64.4 (30.79)	-2.2 (3.85)	85.3 (15.20)	-6.7 (13.33)
	Median	46.7	0.0	86.7	0.0
	Q1, Q3	46.7, 100.0	-6.7, 0.0	73.3, 100.0	-13.3, 0.0
	Min, Max	47, 100	-7, 0	67, 100	-27, 7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	91.1 (7.70)	24.4 (21.43)	88.9 (13.88)	-4.4 (13.88)
	Median	86.7	33.3	93.3	0.0
	Q1, Q3	86.7, 100.0	0.0, 40.0	73.3, 100.0	-20.0, 6.7
	Min, Max	87, 100	0, 40	73, 100	-20, 7
Cycle 16	n	3	3	2	2
	Mean (SD)	75.6 (23.41)	8.9 (15.40)	83.3 (23.57)	-10.0 (23.57)
	Median	73.3	0.0	83.3	-10.0
	Q1, Q3	53.3, 100.0	0.0, 26.7	66.7, 100.0	-26.7, 6.7
	Min, Max	53, 100	0, 27	67, 100	-27, 7
Cycle 18	n	3	3	3	3
	Mean (SD)	73.3 (24.04)	6.7 (11.55)	75.6 (10.18)	-15.6 (13.88)
	Median	66.7	0.0	73.3	-20.0
	Q1, Q3	53.3, 100.0	0.0, 20.0	66.7, 86.7	-26.7, 0.0
	Min, Max	53, 100	0, 20	67, 87	-27, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	77.8 (23.41)	11.1 (19.25)	82.2 (13.88)	-8.9 (15.40)
	Median	80.0	0.0	86.7	0.0
	Q1, Q3	53.3, 100.0	0.0, 33.3	66.7, 93.3	-26.7, 0.0
	Min, Max	53, 100	0, 33	67, 93	-27, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	73.3 (30.55)	6.7 (24.04)	93.3 (6.67)	2.2 (3.85)
	Median	80.0	0.0	93.3	0.0
	Q1, Q3	40.0, 100.0	-13.3, 33.3	86.7, 100.0	0.0, 6.7
	Min, Max	40, 100	-13, 33	87, 100	0, 7
Cycle 24	n	2	2	3	3
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	82.2 (10.18)	-8.9 (13.88)
	Median	90.0	16.7	80.0	-13.3
	Q1, Q3	80.0, 100.0	0.0, 33.3	73.3, 93.3	-20.0, 6.7
	Min, Max	80, 100	0, 33	73, 93	-20, 7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	86.7 (18.86)	13.3 (18.86)	90.0 (4.71)	0.0 (9.43)
	Median	86.7	13.3	90.0	0.0
	Q1, Q3	73.3, 100.0	0.0, 26.7	86.7, 93.3	-6.7, 6.7
	Min, Max	73, 100	0, 27	87, 93	-7, 7
Cycle 28	n	2	2	1	1
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	100.0 (NE)	6.7 (NE)
	Median	90.0	16.7	100.0	6.7
	Q1, Q3	80.0, 100.0	0.0, 33.3	100.0, 100.0	6.7, 6.7
	Min, Max	80, 100	0, 33	100, 100	7, 7
Cycle 30	n	2	2	1	1
	Mean (SD)	76.7 (14.14)	26.7 (18.86)	100.0 (NE)	6.7 (NE)
	Median	76.7	26.7	100.0	6.7
	Q1, Q3	66.7, 86.7	13.3, 40.0	100.0, 100.0	6.7, 6.7
	Min, Max	67, 87	13, 40	100, 100	7, 7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	70.0 (23.57)	20.0 (28.28)	93.3 (NE)	0.0 (NE)
	Median	70.0	20.0	93.3	0.0
	Q1, Q3	53.3, 86.7	0.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	53, 87	0, 40	93, 93	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	60.0 (37.71)	10.0 (42.43)	93.3 (NE)	0.0 (NE)
	Median	60.0	10.0	93.3	0.0
	Q1, Q3	33.3, 86.7	-20.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	33, 87	-20, 40	93, 93	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			100.0 (NE)	6.7 (NE)
	Median			100.0	6.7
	Q1, Q3			100.0, 100.0	6.7, 6.7
	Min, Max			100, 100	7, 7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			86.7 (NE)	-6.7 (NE)
	Median			86.7	-6.7
	Q1, Q3			86.7, 86.7	-6.7, -6.7
	Min, Max			87, 87	-7, -7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	89.6 (9.49)	0.7 (20.40)	71.4 (27.23)	-14.8 (17.77)
	Median	86.7	0.0	83.3	-6.7
	Q1, Q3	86.7, 100.0	-13.3, 0.0	60.0, 86.7	-26.7, 0.0
	Min, Max	73, 100	-27, 33	7, 100	-53, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	76.7 (25.66)	-10.0 (9.64)	60.4 (23.39)	-26.7 (15.63)
	Median	83.3	-6.7	66.7	-26.7
	Q1, Q3	63.3, 96.7	-20.0, 0.0	46.7, 80.0	-33.3, -13.3
	Min, Max	27, 100	-27, 0	7, 87	-60, -7

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.1 (21.12)		79.4 (26.70)	
	Median	100.0		100.0	
	Q1, Q3	75.0, 100.0		66.7, 100.0	
	Min, Max	33, 100		17, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	88.3 (17.66)	3.3 (7.03)	71.1 (31.16)	-8.9 (18.76)
	Median	100.0	0.0	83.3	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 17	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	88.3 (22.29)	3.3 (10.54)	70.8 (29.41)	-9.7 (18.06)
	Median	100.0	0.0	75.0	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 91.7	-16.7, 0.0
	Min, Max	33, 100	0, 33	0, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	83.3 (33.33)	-1.9 (26.93)	70.8 (32.66)	-9.7 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	85.4 (27.37)	-2.1 (5.89)	78.8 (21.20)	-7.6 (18.80)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	90.5 (25.20)	0.0 (0.00)	79.6 (18.22)	-7.4 (16.90)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	0, 0	50, 100	-33, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	83.3 (28.87)	-2.4 (6.30)	95.2 (12.60)	0.0 (19.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	50.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-17, 0	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	58.3 (50.00)	-16.7 (19.25)	88.9 (27.22)	-5.6 (32.77)
	Median	66.7	-16.7	100.0	0.0
	Q1, Q3	16.7, 100.0	-33.3, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	55.6 (50.92)	-11.1 (19.25)	73.3 (30.28)	-20.0 (21.73)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	0.0, 100.0	-33.3, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-50, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	16.7 (16.67)	83.3 (28.87)	-16.7 (28.87)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	50.0, 100.0	-50.0, 0.0
	Min, Max	67, 100	0, 33	50, 100	-50, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	66.7 (33.33)	0.0 (0.00)	83.3 (23.57)	-16.7 (23.57)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	33.3, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	0, 0	67, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (38.49)	-11.1 (19.25)	88.9 (19.25)	-11.1 (19.25)
	Median	33.3	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	55.6 (50.92)	-11.1 (50.92)	88.9 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-67, 33	67, 100	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	72.2 (25.46)	5.6 (25.46)	83.3 (16.67)	-16.7 (16.67)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	50.0, 100.0	-16.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	50, 100	-17, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	83.3 (16.67)	-16.7 (16.67)
	Median	83.3	16.7	83.3	-16.7
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	100.0 (0.00)	0.0 (0.00)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 33	100, 100	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	100.0 (NE)	0.0 (NE)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 33	100, 100	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	66.7 (0.00)	16.7 (23.57)	100.0 (NE)	0.0 (NE)
	Median	66.7	16.7	100.0	0.0
	Q1, Q3	66.7, 66.7	0.0, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	67, 67	0, 33	100, 100	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	33.3 (47.14)	-16.7 (70.71)	100.0 (NE)	0.0 (NE)
	Median	33.3	-16.7	100.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	0, 67	-67, 33	100, 100	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	0.0 (47.14)	100.0 (NE)	0.0 (NE)
	Median	50.0	0.0	100.0	0.0
	Q1, Q3	33.3, 66.7	-33.3, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-33, 33	100, 100	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-16.7 (NE)
	Median			83.3	-16.7
	Q1, Q3			83.3, 83.3	-16.7, -16.7
	Min, Max			83, 83	-17, -17
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
End of Treatment	n	9	9	14	14
	Mean (SD)	87.0 (16.20)	0.0 (22.05)	67.9 (30.29)	-9.5 (15.63)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	67, 100	-33, 33	0, 100	-50, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	69.4 (36.81)	-16.7 (20.10)	53.9 (29.77)	-25.5 (18.74)
	Median	75.0	-16.7	66.7	-33.3
	Q1, Q3	58.3, 100.0	-25.0, 0.0	33.3, 66.7	-33.3, -16.7
	Min, Max	0, 100	-67, 0	0, 100	-67, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	72.9 (27.55)		75.5 (20.08)	
	Median	83.3		75.0	
	Q1, Q3	62.5, 87.5		66.7, 91.7	
	Min, Max	8, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	90.8 (9.98)	15.8 (19.42)	73.9 (19.89)	-1.1 (22.90)
	Median	91.7	8.3	75.0	0.0
	Q1, Q3	83.3, 100.0	8.3, 16.7	66.7, 83.3	-16.7, 0.0
	Min, Max	75, 100	0, 67	17, 100	-25, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	94.2 (11.15)	19.2 (23.59)	75.0 (12.31)	0.7 (17.21)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	91.7, 100.0	8.3, 16.7	66.7, 83.3	-8.3, 8.3
	Min, Max	67, 100	0, 83	50, 100	-25, 42

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	87.0 (20.46)	13.0 (17.73)	75.0 (22.47)	0.7 (16.84)
	Median	100.0	16.7	79.2	0.0
	Q1, Q3	83.3, 100.0	0.0, 16.7	62.5, 91.7	-8.3, 8.3
	Min, Max	42, 100	-17, 42	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	89.6 (15.27)	14.6 (15.91)	75.8 (19.17)	0.8 (22.19)
	Median	95.8	12.5	83.3	0.0
	Q1, Q3	83.3, 100.0	4.2, 16.7	66.7, 83.3	-8.3, 16.7
	Min, Max	58, 100	0, 50	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	10.7 (7.93)	77.8 (18.63)	-2.8 (18.16)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 16.7	66.7, 91.7	-16.7, 8.3
	Min, Max	67, 100	0, 17	42, 100	-25, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	89.3 (14.20)	15.5 (20.65)	86.9 (10.60)	3.6 (10.60)
	Median	100.0	16.7	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 16.7	83.3, 91.7	0.0, 8.3
	Min, Max	67, 100	0, 58	67, 100	-8, 25
Cycle 10	n	4	4	6	6
	Mean (SD)	79.2 (14.43)	16.7 (28.87)	86.1 (26.70)	2.8 (21.52)
	Median	79.2	8.3	100.0	4.2
	Q1, Q3	66.7, 91.7	0.0, 33.3	83.3, 100.0	0.0, 8.3
	Min, Max	67, 92	-8, 58	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	94.4 (9.62)	38.9 (47.39)	81.7 (27.89)	1.7 (23.86)
	Median	100.0	25.0	91.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 91.7	83.3, 100.0	0.0, 8.3
	Min, Max	83, 100	0, 92	33, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	86.1 (12.73)	30.6 (33.68)	80.6 (12.73)	0.0 (16.67)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 66.7	66.7, 91.7	-16.7, 16.7
	Min, Max	75, 100	0, 67	67, 92	-17, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (35.36)	-12.5 (17.68)
	Median	66.7	8.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	0.0, 58.3	41.7, 91.7	-25.0, 0.0
	Min, Max	67, 100	0, 58	42, 92	-25, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	80.6 (17.35)	25.0 (30.05)	83.3 (16.67)	-2.8 (4.81)
	Median	75.0	16.7	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 58.3	66.7, 100.0	-8.3, 0.0
	Min, Max	67, 100	0, 58	67, 100	-8, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	38.9 (37.58)	86.1 (24.06)	0.0 (8.33)
	Median	100.0	41.7	100.0	0.0
	Q1, Q3	83.3, 100.0	0.0, 75.0	58.3, 100.0	-8.3, 8.3
	Min, Max	83, 100	0, 75	58, 100	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (8.33)	-19.4 (24.06)
	Median	66.7	8.3	66.7	-33.3
	Q1, Q3	66.7, 100.0	0.0, 58.3	58.3, 75.0	-33.3, 8.3
	Min, Max	67, 100	0, 58	58, 75	-33, 8
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	4.2 (5.89)	75.0 (0.00)	-11.1 (17.35)
	Median	83.3	4.2	75.0	-16.7
	Q1, Q3	66.7, 100.0	0.0, 8.3	75.0, 75.0	-25.0, 8.3
	Min, Max	67, 100	0, 8	75, 75	-25, 8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	91.7 (11.79)	12.5 (17.68)	79.2 (17.68)	-16.7 (23.57)
	Median	91.7	12.5	79.2	-16.7
	Q1, Q3	83.3, 100.0	0.0, 25.0	66.7, 91.7	-33.3, 0.0
	Min, Max	83, 100	0, 25	67, 92	-33, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	87.5 (17.68)	8.3 (11.79)	83.3 (NE)	-8.3 (NE)
	Median	87.5	8.3	83.3	-8.3
	Q1, Q3	75.0, 100.0	0.0, 16.7	83.3, 83.3	-8.3, -8.3
	Min, Max	75, 100	0, 17	83, 83	-8, -8
Cycle 30	n	2	2	1	1
	Mean (SD)	83.3 (11.79)	50.0 (47.14)	83.3 (NE)	-8.3 (NE)
	Median	83.3	50.0	83.3	-8.3
	Q1, Q3	75.0, 91.7	16.7, 83.3	83.3, 83.3	-8.3, -8.3
	Min, Max	75, 92	17, 83	83, 83	-8, -8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	70.8 (5.89)	37.5 (41.25)	83.3 (NE)	-8.3 (NE)
	Median	70.8	37.5	83.3	-8.3
	Q1, Q3	66.7, 75.0	8.3, 66.7	83.3, 83.3	-8.3, -8.3
	Min, Max	67, 75	8, 67	83, 83	-8, -8
Cycle 34	n	2	2	1	1
	Mean (SD)	75.0 (35.36)	41.7 (0.00)	66.7 (NE)	-25.0 (NE)
	Median	75.0	41.7	66.7	-25.0
	Q1, Q3	50.0, 100.0	41.7, 41.7	66.7, 66.7	-25.0, -25.0
	Min, Max	50, 100	42, 42	67, 67	-25, -25
Cycle 36	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-8.3 (NE)
	Median			83.3	-8.3
	Q1, Q3			83.3, 83.3	-8.3, -8.3
	Min, Max			83, 83	-8, -8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-8.3 (NE)
	Median			83.3	-8.3
	Q1, Q3			83.3, 83.3	-8.3, -8.3
	Min, Max			83, 83	-8, -8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
End of Treatment	n	9	9	14	14
	Mean (SD)	88.0 (15.09)	6.5 (24.92)	72.6 (22.75)	-5.4 (17.17)
	Median	91.7	8.3	75.0	0.0
	Q1, Q3	91.7, 100.0	0.0, 16.7	66.7, 91.7	-25.0, 8.3
	Min, Max	58, 100	-42, 42	25, 100	-33, 25

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	70.8 (23.44)	-2.1 (18.84)	58.8 (19.43)	-16.7 (13.82)
	Median	75.0	0.0	66.7	-16.7
	Q1, Q3	62.5, 87.5	-12.5, 8.3	41.7, 75.0	-25.0, -8.3
	Min, Max	17, 100	-42, 33	17, 83	-33, 8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	94.4 (14.79)		78.4 (18.41)	
	Median	100.0		83.3	
	Q1, Q3	100.0, 100.0		66.7, 100.0	
	Min, Max	50, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	93.3 (11.65)	0.0 (17.57)	75.6 (28.78)	-1.1 (17.21)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-33, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	91.7 (21.15)	-1.7 (9.46)	80.6 (17.16)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-8.3, 0.0
	Min, Max	33, 100	-17, 17	50, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	94.4 (11.79)	1.9 (10.02)	80.6 (24.45)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	75.0, 100.0	0.0, 16.7
	Min, Max	67, 100	-17, 17	33, 100	-50, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	87.5 (23.15)	-6.3 (17.68)	83.3 (26.87)	0.0 (27.89)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 16.7
	Min, Max	50, 100	-50, 0	33, 100	-50, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	92.9 (18.90)	0.0 (0.00)	83.3 (16.67)	0.0 (16.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	50, 100	-33, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	90.5 (16.27)	-2.4 (15.00)	90.5 (13.11)	7.1 (16.27)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	67, 100	-33, 17	67, 100	-17, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	87.5 (25.00)	0.0 (0.00)	83.3 (25.82)	0.0 (18.26)
	Median	100.0	0.0	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	33, 100	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	77.8 (38.49)	-5.6 (9.62)	73.3 (27.89)	-6.7 (27.89)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	33.3, 100.0	-16.7, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	77.8 (19.25)	0.0 (0.00)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	66.7 (47.14)	-16.7 (23.57)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 16.7	33.3, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 17	33, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	88.9 (9.62)	5.6 (25.46)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	83.3, 100.0	-16.7, 33.3	66.7, 100.0	0.0, 0.0
	Min, Max	83, 100	-17, 33	67, 100	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	83, 100	0, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (0.00)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (NE)	0.0 (NE)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (NE)	0.0 (NE)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	75.0 (11.79)	0.0 (23.57)	100.0 (NE)	0.0 (NE)
	Median	75.0	0.0	100.0	0.0
	Q1, Q3	66.7, 83.3	-16.7, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 83	-17, 17	100, 100	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	100.0 (NE)	0.0 (NE)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	100, 100	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-16.7 (NE)
	Median			83.3	-16.7
	Q1, Q3			83.3, 83.3	-16.7, -16.7
	Min, Max			83, 83	-17, -17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	98.1 (5.56)	5.6 (11.79)	73.8 (29.03)	-4.8 (18.98)
	Median	100.0	0.0	75.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	83, 100	0, 33	0, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	84.7 (24.06)	-9.7 (19.41)	61.8 (27.49)	-16.7 (19.54)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	-25.0, 0.0	33.3, 83.3	-33.3, 0.0
	Min, Max	33, 100	-50, 17	0, 100	-50, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	83.3 (21.32)		80.4 (17.91)	
	Median	91.7		83.3	
	Q1, Q3	66.7, 100.0		66.7, 100.0	
	Min, Max	33, 100		50, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	85.0 (18.34)	0.0 (15.71)	68.9 (28.08)	-10.0 (23.40)
	Median	91.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	-17, 33	0, 100	-67, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	90.0 (17.92)	5.0 (11.25)	76.4 (21.86)	-6.9 (19.41)
	Median	100.0	0.0	75.0	-8.3
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 33	33, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.2 (17.57)	0.0 (16.67)	69.4 (25.46)	-13.9 (19.89)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 0.0	50.0, 91.7	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	91.7 (15.43)	0.0 (17.82)	71.2 (24.82)	-15.2 (22.92)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-50, 17
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	4.8 (12.60)	83.3 (16.67)	-5.6 (18.63)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	85.7 (17.82)	-4.8 (23.00)	88.1 (15.85)	-2.4 (20.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	-33, 33	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (43.03)	-41.7 (41.94)	83.3 (27.89)	-5.6 (25.09)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	16.7, 83.3	-66.7, -16.7	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-100, 0	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	83.3 (28.87)	-3.3 (24.72)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	33, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 0	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	58.3 (35.36)	-25.0 (11.79)
	Median	66.7	0.0	58.3	-25.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	33.3, 83.3	-33.3, -16.7
	Min, Max	67, 100	-33, 0	33, 83	-33, -17
Cycle 18	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	66.7 (33.33)	-22.2 (38.49)	83.3 (16.67)	-5.6 (9.62)
	Median	66.7	0.0	83.3	0.0
	Q1, Q3	33.3, 100.0	-66.7, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-67, 0	67, 100	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	77.8 (19.25)	-11.1 (19.25)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	91.7 (11.79)	-8.3 (11.79)
	Median	83.3	0.0	91.7	-8.3
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	83, 100	-17, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	66.7 (NE)	-33.3 (NE)
	Median	83.3	0.0	66.7	-33.3
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 66.7	-33.3, -33.3
	Min, Max	67, 100	0, 0	67, 67	-33, -33
Cycle 30	n	2	2	1	1
	Mean (SD)	66.7 (0.00)	-16.7 (23.57)	83.3 (NE)	-16.7 (NE)
	Median	66.7	-16.7	83.3	-16.7
	Q1, Q3	66.7, 66.7	-33.3, 0.0	83.3, 83.3	-16.7, -16.7
	Min, Max	67, 67	-33, 0	83, 83	-17, -17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	-33.3 (47.14)	100.0 (NE)	0.0 (NE)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	33.3, 66.7	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-67, 0	100, 100	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	-33.3 (47.14)	100.0 (NE)	0.0 (NE)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	33.3, 66.7	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-67, 0	100, 100	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
End of Treatment	n	9	9	14	14
	Mean (SD)	87.0 (20.03)	7.4 (16.90)	69.0 (35.12)	-11.9 (26.50)
	Median	100.0	0.0	75.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	-33.3, 0.0
	Min, Max	50, 100	-17, 33	0, 100	-67, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	65.3 (29.69)	-18.1 (29.69)	51.0 (27.30)	-29.4 (18.19)
	Median	66.7	-16.7	66.7	-33.3
	Q1, Q3	50.0, 91.7	-25.0, 0.0	33.3, 66.7	-33.3, -16.7
	Min, Max	0, 100	-100, 17	0, 100	-67, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	24.1 (31.72)		33.3 (22.57)	
	Median	5.6		33.3	
	Q1, Q3	0.0, 50.0		22.2, 44.4	
	Min, Max	0, 89		0, 78	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.6 (21.72)	-8.9 (23.31)	41.5 (26.05)	9.6 (18.24)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-11.1, 0.0	22.2, 44.4	0.0, 22.2
	Min, Max	0, 56	-67, 22	0, 100	-11, 56
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (25.01)	-4.4 (15.89)	39.8 (23.43)	8.3 (13.50)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 44.4	-11.1, 0.0	27.8, 55.6	0.0, 16.7
	Min, Max	0, 67	-44, 11	11, 89	-11, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	23.5 (30.65)	-1.2 (10.31)	42.6 (28.36)	11.1 (22.72)
	Median	11.1	0.0	44.4	5.6
	Q1, Q3	0.0, 33.3	0.0, 0.0	16.7, 61.1	0.0, 33.3
	Min, Max	0, 89	-22, 11	0, 89	-33, 44
Cycle 5	n	8	8	11	11
	Mean (SD)	15.3 (25.85)	-5.6 (10.29)	32.3 (26.04)	5.1 (20.71)
	Median	0.0	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	-11.1, 0.0	11.1, 44.4	0.0, 22.2
	Min, Max	0, 67	-22, 0	0, 89	-44, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	12.7 (25.20)	1.6 (4.20)	29.6 (21.52)	1.2 (15.16)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 22.2	0.0, 0.0	22.2, 33.3	-11.1, 11.1
	Min, Max	0, 67	0, 11	0, 78	-22, 22

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	25.4 (36.69)	1.6 (7.67)	11.1 (15.71)	-12.7 (16.27)
	Median	0.0	0.0	0.0	-11.1
	Q1, Q3	0.0, 77.8	0.0, 11.1	0.0, 33.3	-22.2, 0.0
	Min, Max	0, 78	-11, 11	0, 33	-44, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (46.70)	8.3 (18.98)	18.5 (30.36)	-9.3 (25.74)
	Median	50.0	5.6	5.6	-11.1
	Q1, Q3	11.1, 88.9	-5.6, 22.2	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 100	-11, 33	0, 78	-44, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	40.7 (52.51)	-11.1 (50.92)	33.3 (15.71)	0.0 (11.11)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	33.3, 33.3	-11.1, 11.1
	Min, Max	0, 100	-67, 33	11, 56	-11, 11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (11.11)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-22.2, 0.0
	Min, Max	0, 33	-56, 0	11, 33	-22, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	29.6 (33.95)	-22.2 (38.49)	33.3 (31.43)	0.0 (15.71)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	11.1, 55.6	-11.1, 11.1
	Min, Max	0, 67	-67, 0	11, 56	-11, 11
Cycle 18	n	3	3	3	3
	Mean (SD)	37.0 (39.02)	-14.8 (16.97)	25.9 (16.97)	-7.4 (6.42)
	Median	33.3	-11.1	22.2	-11.1
	Q1, Q3	0.0, 77.8	-33.3, 0.0	11.1, 44.4	-11.1, 0.0
	Min, Max	0, 78	-33, 0	11, 44	-11, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (0.00)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-11.1, -11.1
	Min, Max	0, 33	-56, 0	11, 33	-11, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (22.22)	-29.6 (25.66)	37.0 (6.42)	3.7 (6.42)
	Median	22.2	-44.4	33.3	0.0
	Q1, Q3	0.0, 44.4	-44.4, 0.0	33.3, 44.4	0.0, 11.1
	Min, Max	0, 44	-44, 0	33, 44	0, 11
Cycle 24	n	2	2	3	3
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	37.0 (12.83)	3.7 (16.97)
	Median	11.1	-22.2	44.4	0.0
	Q1, Q3	0.0, 22.2	-44.4, 0.0	22.2, 44.4	-11.1, 22.2
	Min, Max	0, 22	-44, 0	22, 44	-11, 22

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	16.7 (7.86)	-11.1 (0.00)
	Median	11.1	-22.2	16.7	-11.1
	Q1, Q3	0.0, 22.2	-44.4, 0.0	11.1, 22.2	-11.1, -11.1
	Min, Max	0, 22	-44, 0	11, 22	-11, -11
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	33.3 (NE)	11.1 (NE)
	Median	16.7	-16.7	33.3	11.1
	Q1, Q3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	11.1, 11.1
	Min, Max	0, 33	-33, 0	33, 33	11, 11
Cycle 30	n	2	2	1	1
	Mean (SD)	33.3 (0.00)	-44.4 (15.71)	11.1 (NE)	-11.1 (NE)
	Median	33.3	-44.4	11.1	-11.1
	Q1, Q3	33.3, 33.3	-55.6, -33.3	11.1, 11.1	-11.1, -11.1
	Min, Max	33, 33	-56, -33	11, 11	-11, -11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	61.1 (55.00)	-16.7 (39.28)	22.2 (NE)	0.0 (NE)
	Median	61.1	-16.7	22.2	0.0
	Q1, Q3	22.2, 100.0	-44.4, 11.1	22.2, 22.2	0.0, 0.0
	Min, Max	22, 100	-44, 11	22, 22	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	55.6 (31.43)	-22.2 (15.71)	33.3 (NE)	11.1 (NE)
	Median	55.6	-22.2	33.3	11.1
	Q1, Q3	33.3, 77.8	-33.3, -11.1	33.3, 33.3	11.1, 11.1
	Min, Max	33, 78	-33, -11	33, 33	11, 11
Cycle 36	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
End of Treatment	n	9	9	14	14
	Mean (SD)	18.5 (14.70)	1.2 (18.79)	42.1 (25.48)	8.7 (16.98)
	Median	22.2	0.0	33.3	5.6
	Q1, Q3	0.0, 33.3	0.0, 11.1	22.2, 66.7	0.0, 22.2
	Min, Max	0, 33	-33, 22	0, 89	-22, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.0 (36.22)	13.9 (13.50)	58.8 (26.58)	25.5 (15.60)
	Median	22.2	11.1	55.6	33.3
	Q1, Q3	11.1, 61.1	5.6, 22.2	44.4, 77.8	22.2, 33.3
	Min, Max	0, 100	-11, 33	11, 100	0, 56

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	5.6 (10.86)		8.8 (16.79)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 8.3		0.0, 16.7	
	Min, Max	0, 33		0, 50	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (13.15)	20.0 (20.12)	10.0 (13.80)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 17	0, 67	-17, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-1.7 (9.46)	15.3 (20.67)	12.5 (23.70)
	Median	0.0	0.0	8.3	8.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 25.0	0.0, 25.0
	Min, Max	0, 17	-17, 17	0, 67	-17, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (18.84)	3.7 (13.89)	11.1 (12.97)	8.3 (15.08)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 50	-17, 33	0, 33	-17, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (12.60)	2.1 (13.91)	16.7 (19.72)	13.6 (22.13)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-17, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	7.1 (13.11)	4.8 (12.60)	22.2 (18.63)	18.5 (21.15)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 50	-17, 50

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (19.25)	7.1 (8.91)	2.4 (15.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	-16.7, 16.7
	Min, Max	0, 33	-33, 33	0, 17	-17, 17
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-4.2 (28.46)	5.6 (13.61)	0.0 (10.54)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-25.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	-17, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (25.46)	10.0 (22.36)	3.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 17	0, 50	-17, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	16.7 (23.57)	8.3 (11.79)
	Median	0.0	0.0	16.7	8.3
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (9.62)	5.6 (9.62)
	Median	0.0	-8.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 17	0, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	8.3 (11.79)	8.3 (11.79)
	Median	0.0	-8.3	8.3	8.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 17	0, 17
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-17, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			16.7 (NE)	16.7 (NE)
	Median			16.7	16.7
	Q1, Q3			16.7, 16.7	16.7, 16.7
	Min, Max			17, 17	17, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			16.7 (NE)	16.7 (NE)
	Median			16.7	16.7
	Q1, Q3			16.7, 16.7	16.7, 16.7
	Min, Max			17, 17	17, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	5.6 (16.67)	3.7 (18.22)	14.3 (15.82)	4.8 (23.05)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-17, 50	0, 33	-50, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	11.1 (20.52)	5.6 (16.41)	35.3 (19.44)	26.5 (18.69)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 8.3	16.7, 50.0	16.7, 33.3
	Min, Max	0, 50	-17, 50	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	18.1 (28.83)		24.5 (31.25)	
	Median	0.0		16.7	
	Q1, Q3	0.0, 25.0		0.0, 33.3	
	Min, Max	0, 83		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.0 (11.25)	-13.3 (26.99)	24.4 (33.25)	1.1 (29.19)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 0.0
	Min, Max	0, 33	-83, 0	0, 100	-50, 83
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-15.0 (24.15)	26.4 (27.02)	5.6 (32.05)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-8.3, 16.7
	Min, Max	0, 17	-67, 0	0, 83	-50, 83

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	13.0 (28.60)	-7.4 (12.11)	20.8 (23.70)	0.0 (26.59)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 83	-33, 0	0, 83	-50, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	6.3 (17.68)	-8.3 (12.60)	21.2 (24.82)	6.1 (22.70)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-33, 0	0, 83	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (16.67)	20.4 (24.69)	5.6 (25.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-33, 50

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.13)	-11.9 (24.93)	7.1 (13.11)	2.4 (20.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-67, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (9.62)	-16.7 (33.33)	11.1 (27.22)	5.6 (32.77)
	Median	8.3	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 17	-67, 0	0, 67	-33, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	16.7 (28.87)	-16.7 (60.09)	20.0 (21.73)	13.3 (21.73)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 50.0	-83.3, 33.3	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-83, 33	0, 50	0, 50

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (16.67)	16.7 (16.67)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (9.62)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-17, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	27.8 (48.11)	-5.6 (9.62)	22.2 (9.62)	22.2 (9.62)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 83.3	-16.7, 0.0	16.7, 33.3	16.7, 33.3
	Min, Max	0, 83	-17, 0	17, 33	17, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-17, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	0.0 (NE)	0.0 (NE)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-17, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-33.3 (23.57)	16.7 (NE)	16.7 (NE)
	Median	16.7	-33.3	16.7	16.7
	Q1, Q3	0.0, 33.3	-50.0, -16.7	16.7, 16.7	16.7, 16.7
	Min, Max	0, 33	-50, -17	17, 17	17, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	0.0 (23.57)	0.0 (NE)	0.0 (NE)
	Median	50.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-17, 17	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	25.0 (35.36)	-25.0 (11.79)	0.0 (NE)	0.0 (NE)
	Median	25.0	-25.0	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 50	-33, -17	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (12.11)	-3.7 (23.24)	36.9 (34.70)	8.3 (29.78)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 66.7	0.0, 16.7
	Min, Max	0, 33	-50, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	26.4 (32.14)	8.3 (19.46)	50.0 (30.05)	25.5 (32.87)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 41.7	0.0, 25.0	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 83

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		15.7 (26.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	24.4 (26.63)	11.1 (20.57)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (23.57)	8.3 (23.57)	12.1 (22.47)	3.0 (10.05)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	14.8 (24.22)	3.7 (11.11)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	25.0 (31.91)	11.1 (27.22)	5.6 (13.61)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	13.3 (18.26)	6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (33.33)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 33.3
	Min, Max	0, 33	0, 33	0, 33	-33, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	11.1 (16.67)	11.1 (16.67)	28.6 (31.64)	11.9 (21.11)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	13.9 (22.29)	13.9 (22.29)	39.2 (26.97)	23.5 (22.87)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 67	0, 67	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (35.77)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 50.0		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	16.7 (28.33)	-10.0 (16.10)	28.9 (30.52)	6.7 (31.37)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 100	-67, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	13.3 (17.21)	-13.3 (39.13)	25.0 (25.13)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	11.1 (16.67)	-18.5 (33.79)	16.7 (17.41)	2.8 (22.29)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	20.8 (24.80)	-12.5 (24.80)	9.1 (21.56)	0.0 (21.08)
	Median	16.7	-16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	-9.5 (16.27)	11.1 (16.67)	3.7 (20.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	28.6 (40.50)	-9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-41.7 (41.94)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-66.7, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-100, 0	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	13.3 (29.81)	6.7 (14.91)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	44.4 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	66.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-44.4 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	-22.2 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	33.3	-33.3	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	33.3 (33.33)	22.2 (38.49)
	Median	16.7	-16.7	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	16.7 (23.57)	16.7 (23.57)
	Median	16.7	-16.7	16.7	16.7
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 33	0, 33
Cycle 28	n	2	2	1	1
	Mean (SD)	33.3 (47.14)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	33.3 (0.00)	-50.0 (23.57)	0.0 (NE)	0.0 (NE)
	Median	33.3	-50.0	0.0	0.0
	Q1, Q3	33.3, 33.3	-66.7, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	-67, -33	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (23.57)	-33.3 (0.00)	0.0 (NE)	0.0 (NE)
	Median	50.0	-33.3	0.0	0.0
	Q1, Q3	33.3, 66.7	-33.3, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 67	-33, -33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	66.7 (47.14)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	66.7	-16.7	0.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	33, 100	-33, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	22.2 (33.33)	3.7 (20.03)	23.8 (33.15)	0.0 (26.15)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-33.3, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	36.1 (36.12)	13.9 (17.16)	51.0 (29.15)	29.4 (28.58)
	Median	33.3	0.0	66.7	33.3
	Q1, Q3	0.0, 50.0	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	10.0 (22.50)	-10.0 (35.31)	31.1 (34.43)	6.7 (25.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (10.54)	-16.7 (32.39)	19.4 (22.29)	5.6 (27.83)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-11.1 (33.33)	25.0 (20.72)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-12.5 (39.59)	27.3 (25.03)	15.2 (34.52)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	25.9 (22.22)	11.1 (37.27)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 0	0, 67	-67, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	-9.5 (41.79)	14.3 (26.23)	0.0 (38.49)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (16.67)	-8.3 (41.94)	11.1 (27.22)	-5.6 (32.77)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	16.7, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	-22.2 (69.39)	13.3 (29.81)	-6.7 (36.51)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-100, 33	0, 67	-67, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-44.4 (50.92)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-66.7 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, -33	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-50.0 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	-50.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, -33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-66.7 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, -33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	14.8 (17.57)	3.7 (26.06)	33.3 (34.59)	9.5 (33.15)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	-67, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.9 (34.33)	16.7 (26.59)	49.0 (29.15)	27.5 (31.70)
	Median	33.3	16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 67	0, 100	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	19.4 (33.21)		17.6 (31.44)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	3.3 (29.19)	22.2 (34.88)	2.2 (23.46)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (28.11)	0.0 (38.49)	16.7 (17.41)	13.9 (22.29)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 33	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	18.5 (33.79)	0.0 (28.87)	11.1 (16.41)	8.3 (20.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	25.0 (38.83)	16.7 (35.63)	9.1 (15.57)	9.1 (15.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 16.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.8 (17.57)	14.8 (17.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	23.8 (41.79)	14.3 (26.23)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 67	0, 0	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	33.3 (47.14)	16.7 (57.74)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-16.7, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 100	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	0.0 (66.67)	13.3 (29.81)	13.3 (29.81)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 67	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 0	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-11.1 (50.92)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 0	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	-16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	50.0	16.7	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (22.22)	-7.4 (36.43)	26.2 (37.39)	4.8 (25.68)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-100, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.9 (42.24)	19.4 (30.01)	35.3 (32.21)	17.6 (29.15)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 83.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		7.8 (14.57)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 0.0	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (14.05)	8.9 (15.26)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	10.0 (16.10)	-3.3 (18.92)	22.2 (25.95)	11.1 (21.71)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-33, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (20.03)	11.1 (21.71)	0.0 (14.21)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (15.43)	-4.2 (11.79)	15.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	0.0 (0.00)	18.5 (24.22)	11.1 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (26.23)	0.0 (19.25)	9.5 (25.20)	0.0 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (33.33)	8.3 (16.67)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	11.1 (19.25)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (14.70)	-11.1 (16.67)	2.4 (8.91)	-4.8 (12.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	19.4 (26.43)	5.6 (12.97)	23.5 (25.72)	15.7 (20.81)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Global health status / QoL									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	63.19 (29.83)	10.50 (4.57)	17	57.84 (25.08)	3.23 (3.46)	7.27 (-3.30, 17.85)	0.58 (-0.26, 1.43)	0.1680

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.67 (21.84)	-1.63 (2.77)	17	87.06 (14.23)	-10.49 (2.10)	8.86 (2.53, 15.19)	1.22 (0.30, 2.14)	0.0081

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.11 (21.12)	6.19 (4.92)	17	79.41 (26.70)	-5.03 (3.64)	11.22 (-0.36, 22.81)	0.79 (-0.04, 1.63)	0.0570

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	72.92 (27.55)	13.40 (5.91)	17	75.49 (20.08)	0.54 (4.17)	12.87 (-0.63, 26.36)	0.79 (-0.06, 1.64)	0.0606

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Cognitive functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	94.44 (14.79)	0.26 (4.26)	17	78.43 (18.41)	-0.92 (3.17)	1.18 (-9.14, 11.51)	0.11 (-0.80, 1.01)	0.8143

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	83.33 (21.32)	4.87 (5.70)	17	80.39 (17.91)	-7.60 (4.20)	12.47 (-0.85, 25.79)	0.78 (-0.07, 1.63)	0.0650

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	24.07 (31.72)	-6.22 (5.46)	17	33.33 (22.57)	5.60 (4.12)	-11.82 (-24.80, 1.15)	-0.76 (-1.60, 0.09)	0.0714

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	5.56 (10.86)	-3.70 (3.58)	17	8.82 (16.79)	9.08 (2.74)	-12.78 (-20.99, -4.57)	-1.35 (-2.29, -0.41)	0.0038

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	18.06 (28.83)	-14.62 (6.52)	17	24.51 (31.25)	3.66 (4.88)	-18.29 (-33.68, -2.89)	-0.99 (-1.87, -0.12)	0.0226

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	2.09 (3.77)	17	15.69 (26.66)	9.88 (2.85)	-7.78 (-16.92, 1.35)	-0.80 (-1.74, 0.15)	0.0907

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Insomnia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (35.77)	-9.34 (4.49)	17	21.57 (31.05)	3.01 (3.58)	-12.35 (-22.58, -2.13)	-1.11 (-2.06, -0.16)	0.0199

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Appetite loss									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	-13.72 (6.40)	17	21.57 (31.05)	2.38 (4.78)	-16.10 (-30.61, -1.59)	-0.97 (-1.88, -0.07)	0.0311

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Constipation									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	19.44 (33.21)	9.79 (6.80)	17	17.65 (31.44)	8.51 (5.01)	1.28 (-14.59, 17.15)	0.07 (-0.76, 0.90)	0.8684

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Diarrhea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-5.26 (3.06)	17	7.84 (14.57)	3.70 (2.39)	-8.96 (-15.84, -2.08)	-1.22 (-2.19, -0.25)	0.0125

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-sa.rtf

Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QoL	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.808 (0.083, 7.837)	0.8539
Physical Functioning	13	2 (15.4)	NR (2.3, NE)	17	8 (47.1)	2.1 (0.9, NE)	0.213 (0.025, 1.787)	0.1173
Role Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.4 (0.7, NE)	0.177 (0.036, 0.879)	0.0198
Emotional Functioning	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	14.7 (2.2, NE)	0.000 (0.000, NE)	0.1326
Cognitive Functioning	13	2 (15.4)	NR (1.4, NE)	17	5 (29.4)	NR (2.2, NE)	0.879 (0.155, 4.997)	0.8846
Social Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.5 (0.8, NE)	0.235 (0.047, 1.179)	0.0586

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-2-1-2-eff-tte-qlq-c30-pop1-sa.rtf

Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Fatigue	13	3 (23.1)	NR (3.7, NE)	17	11 (64.7)	2.1 (0.7, NE)	0.327 (0.079, 1.343)	0.1083
Nausea and Vomiting	13	1 (7.7)	NR (NE, NE)	17	9 (52.9)	4.4 (0.8, NE)	0.135 (0.016, 1.117)	0.0310
Pain	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	NR (2.1, NE)	0.000 (0.000, NE)	0.0539
Dyspnoea	13	3 (23.1)	NR (1.4, NE)	17	4 (23.5)	NR (1.4, NE)	1.714 (0.268, 10.985)	0.5657
Insomnia	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	19.1 (1.4, NE)	0.171 (0.020, 1.450)	0.0687
Appetite Loss	13	2 (15.4)	NR (5.3, NE)	17	8 (47.1)	3.3 (1.4, NE)	0.352 (0.067, 1.851)	0.2032

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Constipation	13	3 (23.1)	NR (0.7, NE)	17	7 (41.2)	NR (0.8, NE)	0.634 (0.150, 2.673)	0.5075
Diarrhea	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.1, NE)	0.536 (0.073, 3.928)	0.5358

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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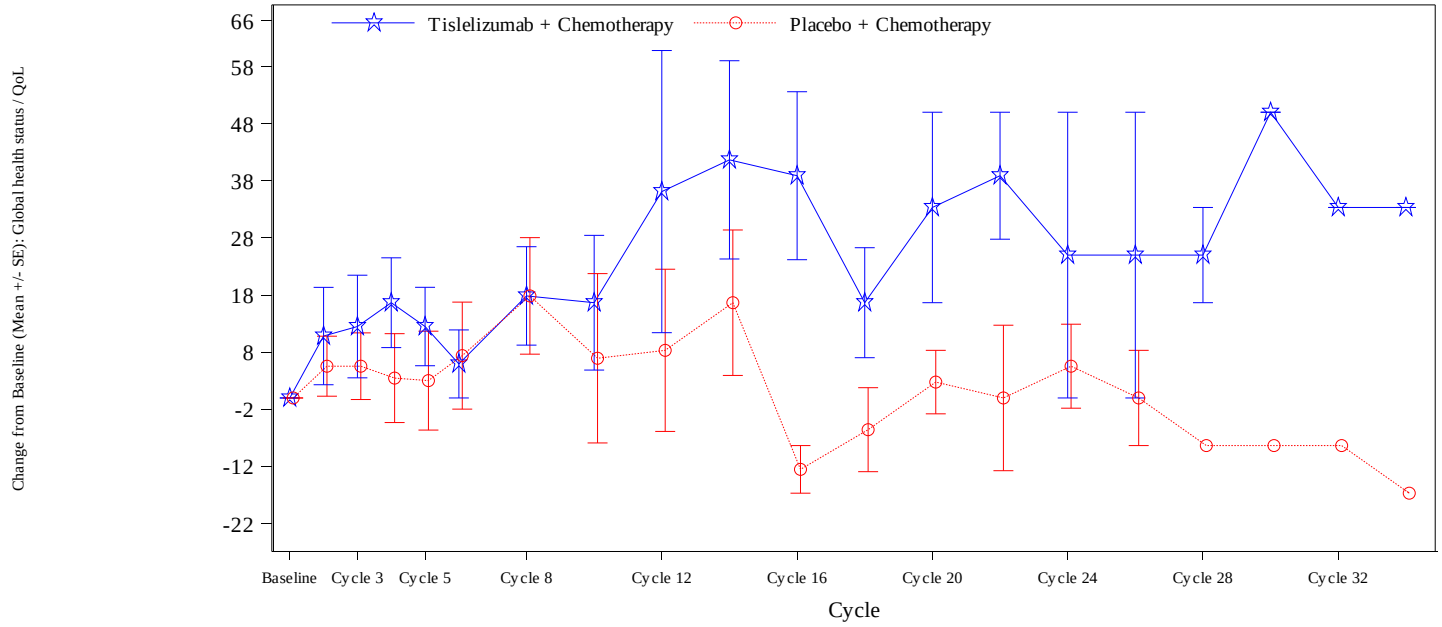
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

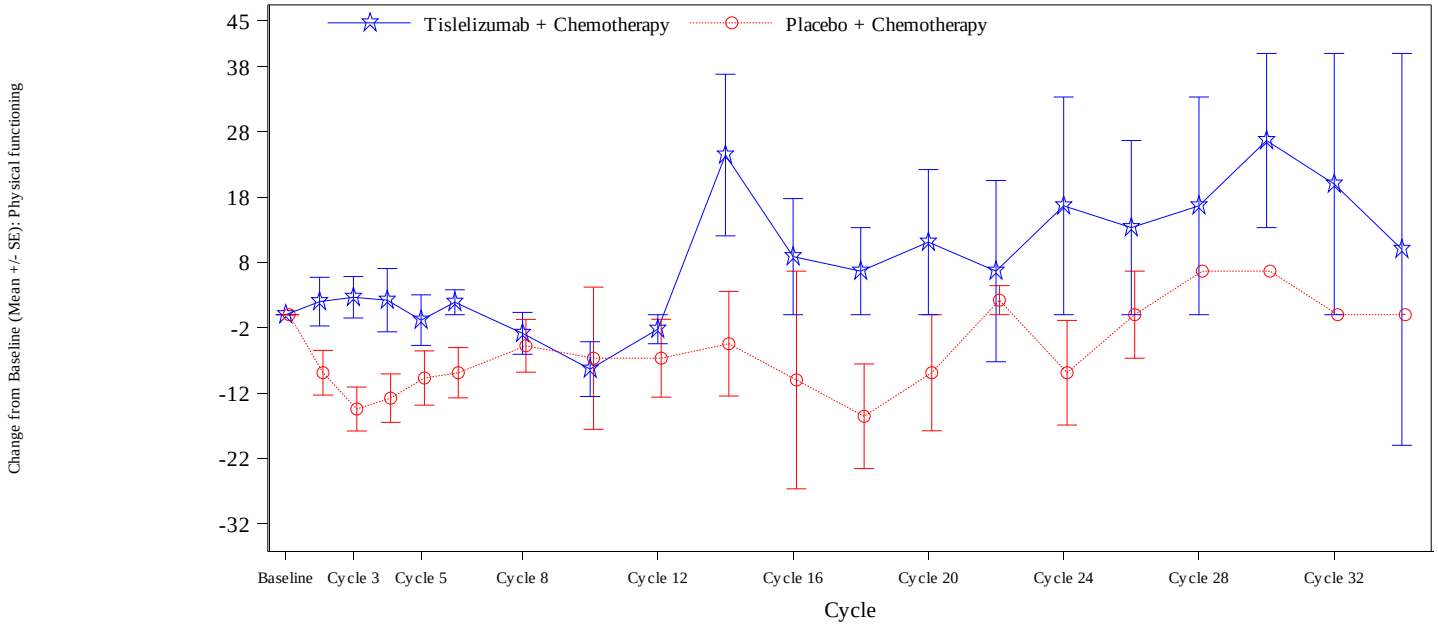


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-1-series-c30-pop1-sa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
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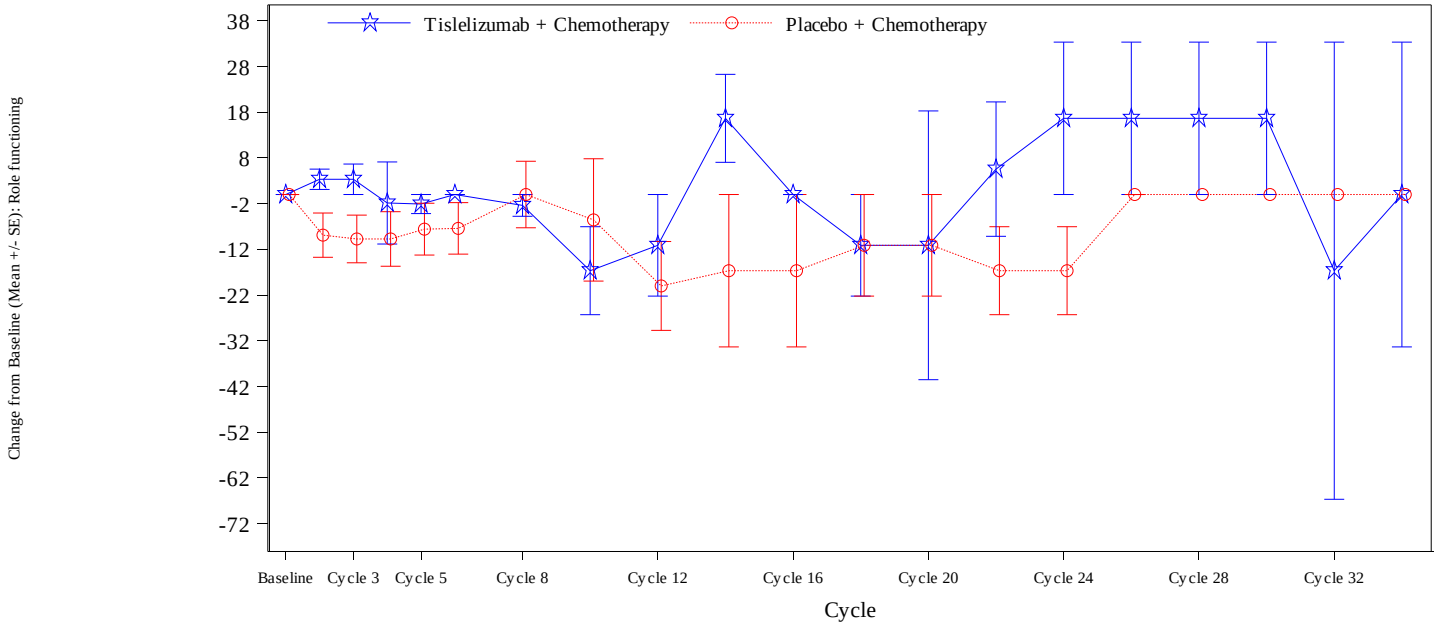
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
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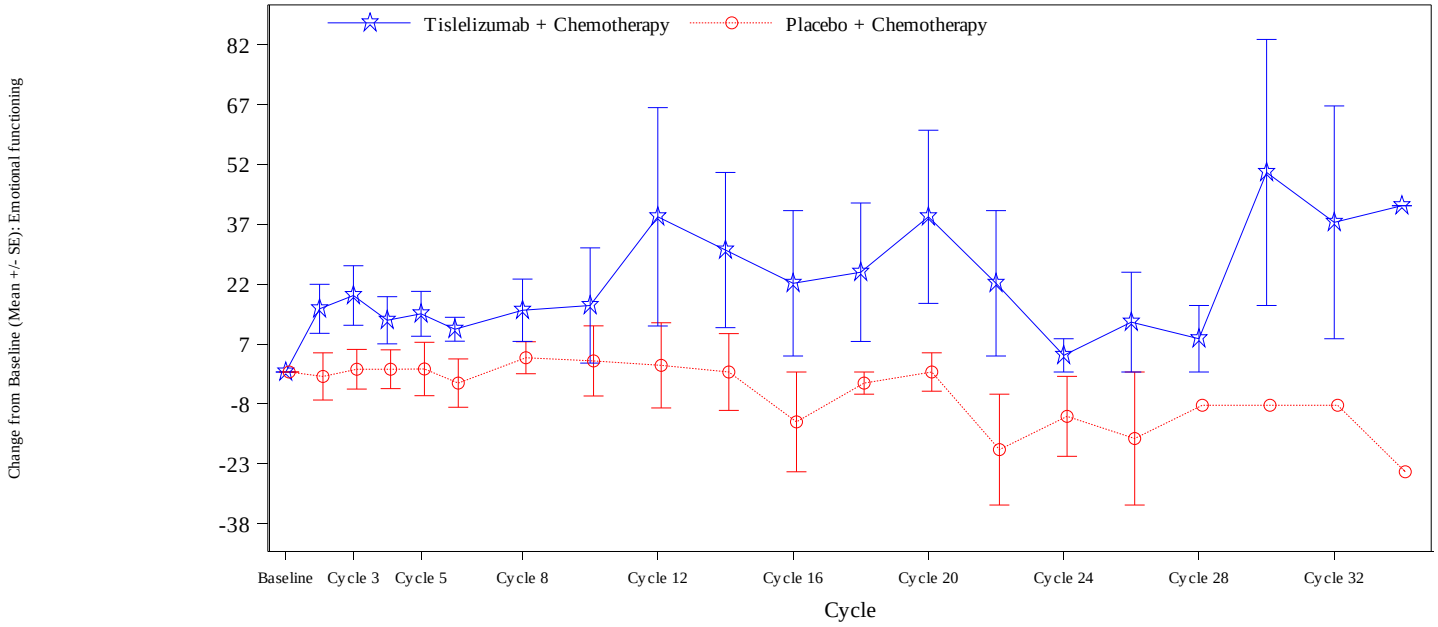
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
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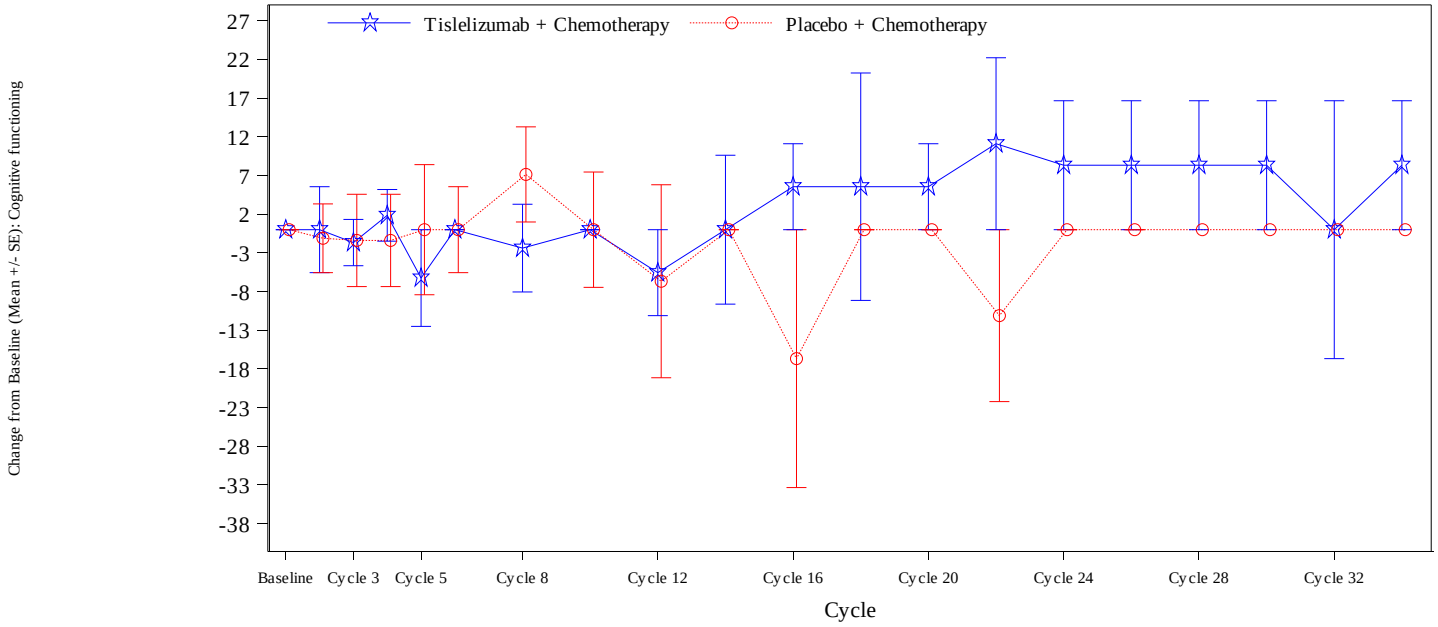
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-1-series-c30-pop1-sa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
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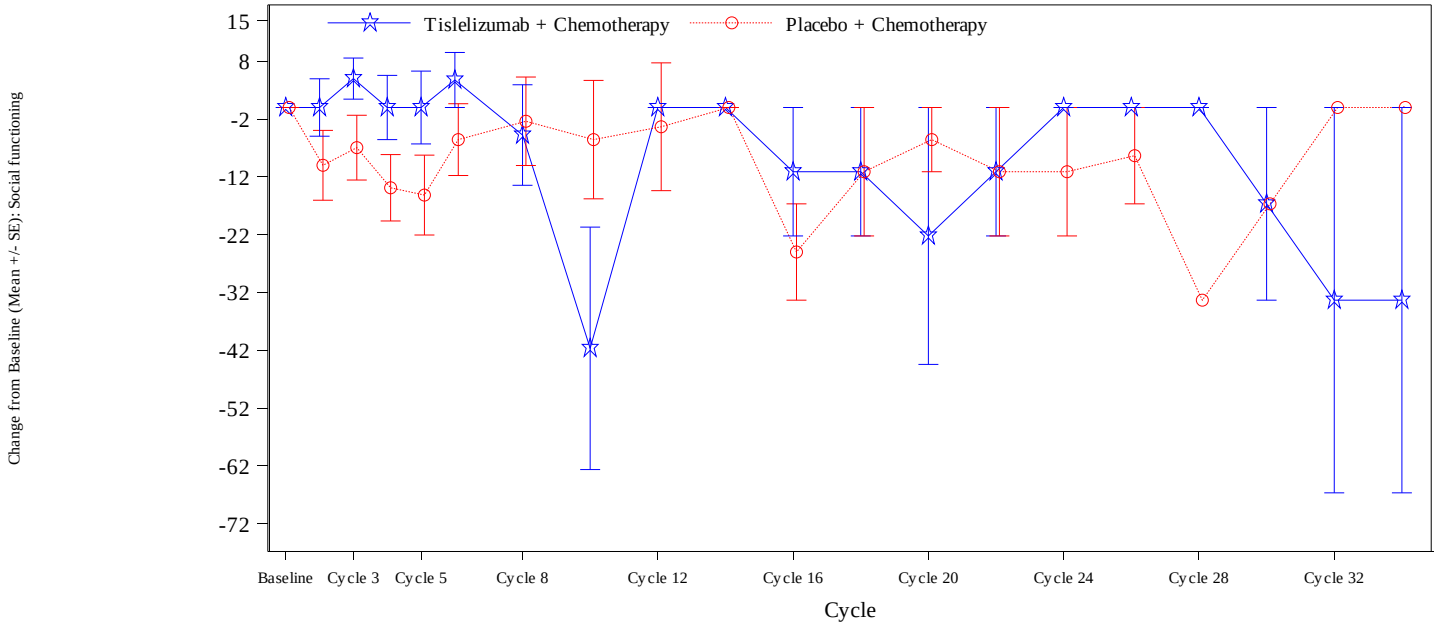

No. of Patients

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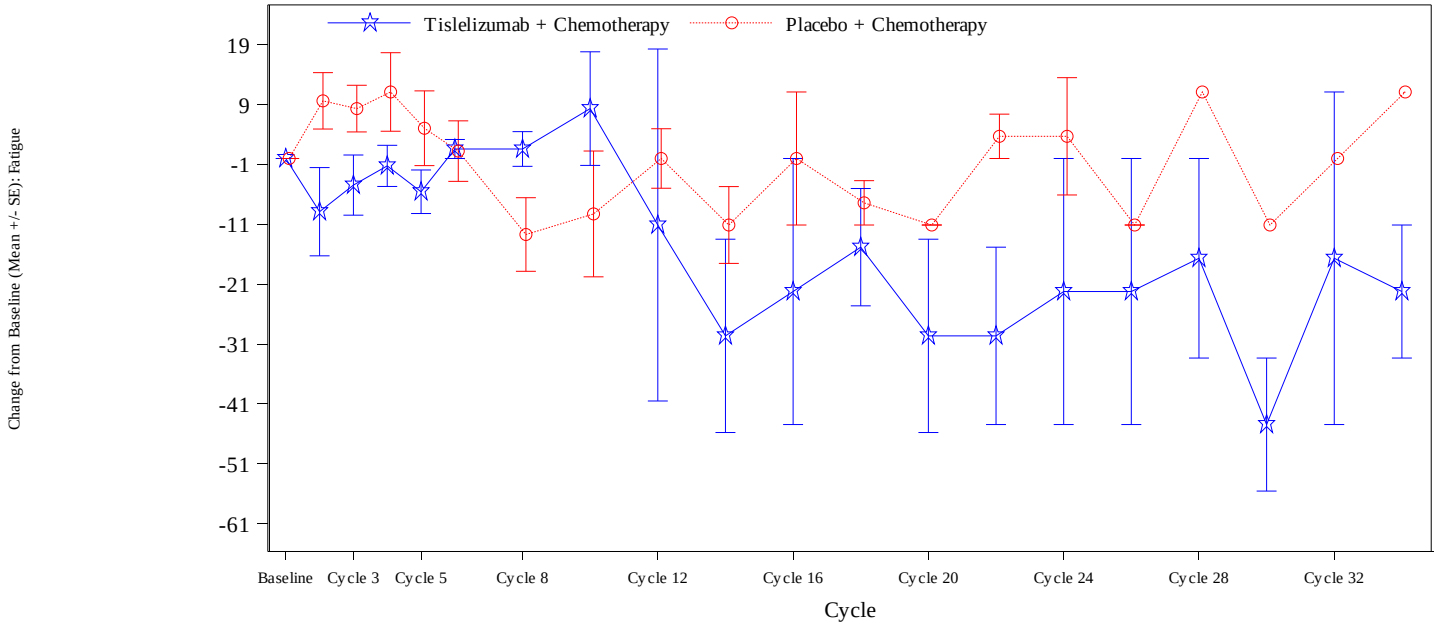

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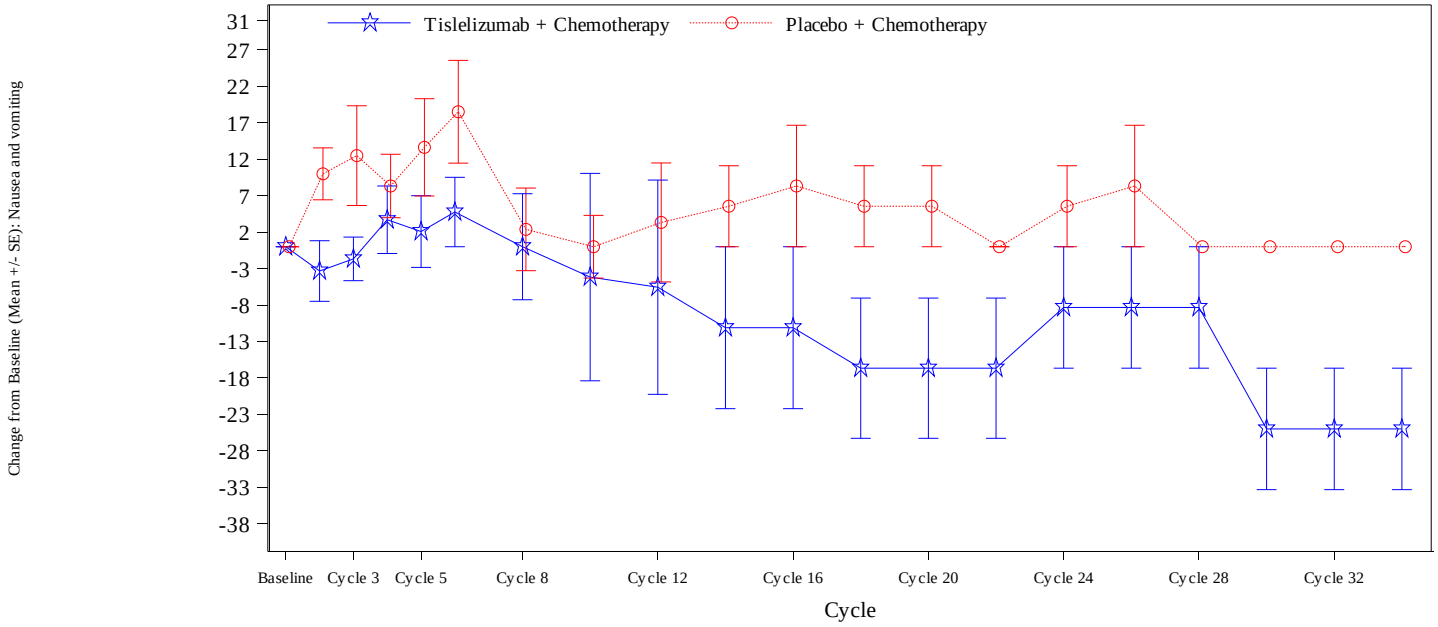

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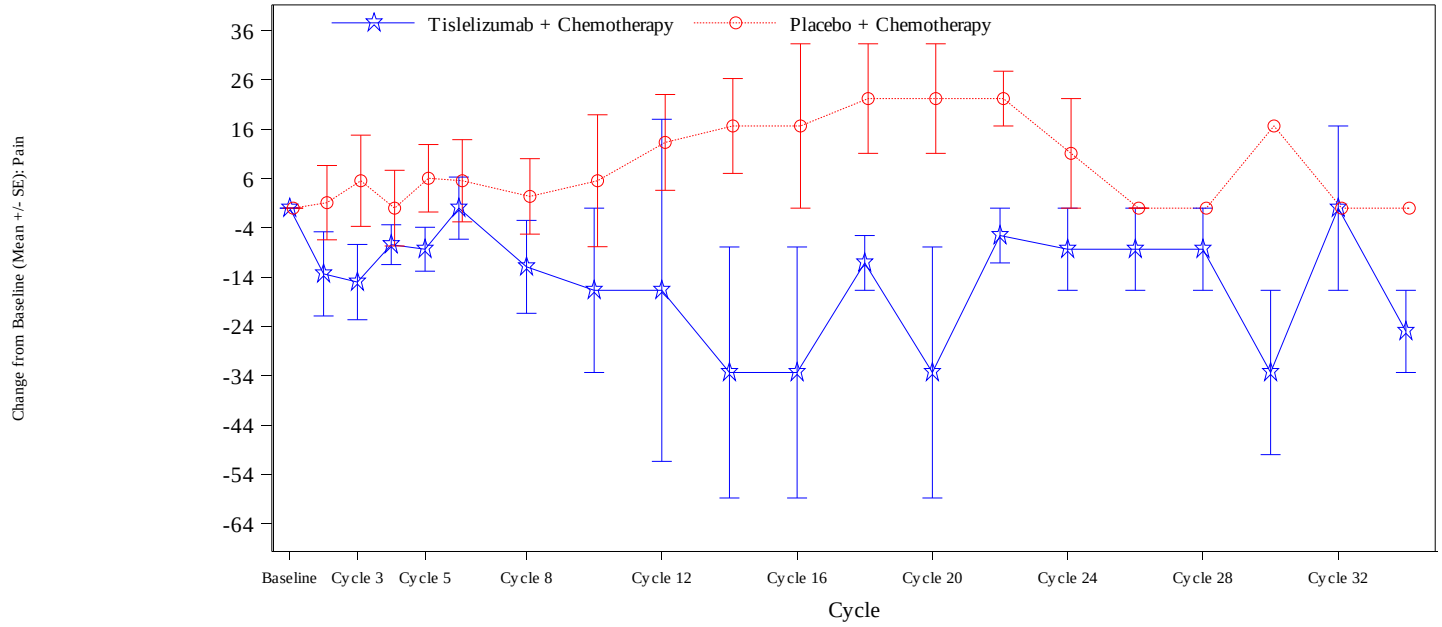

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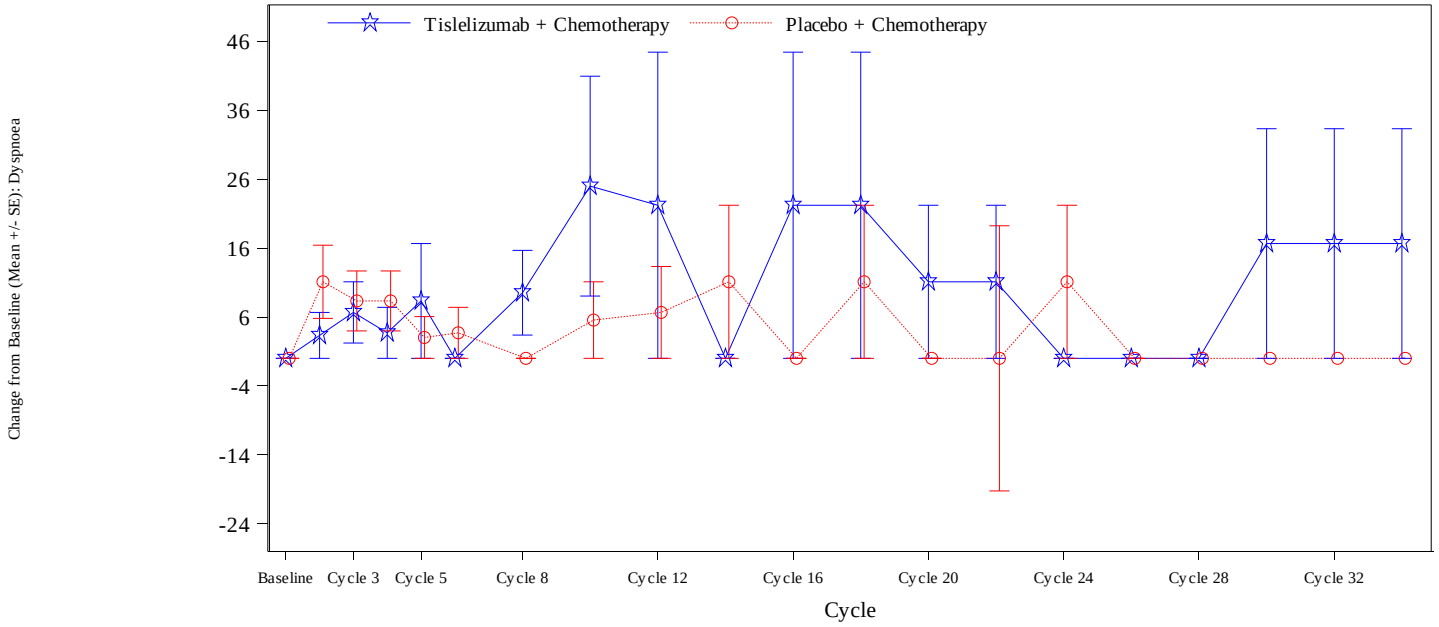

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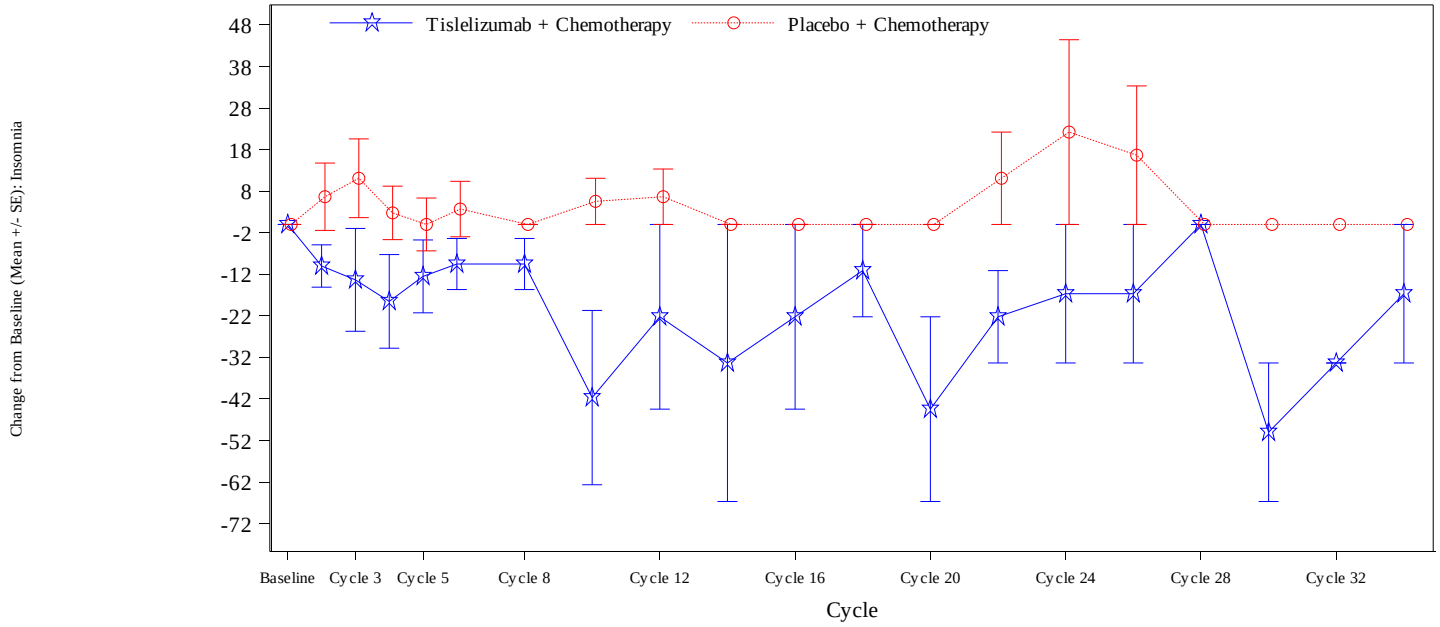

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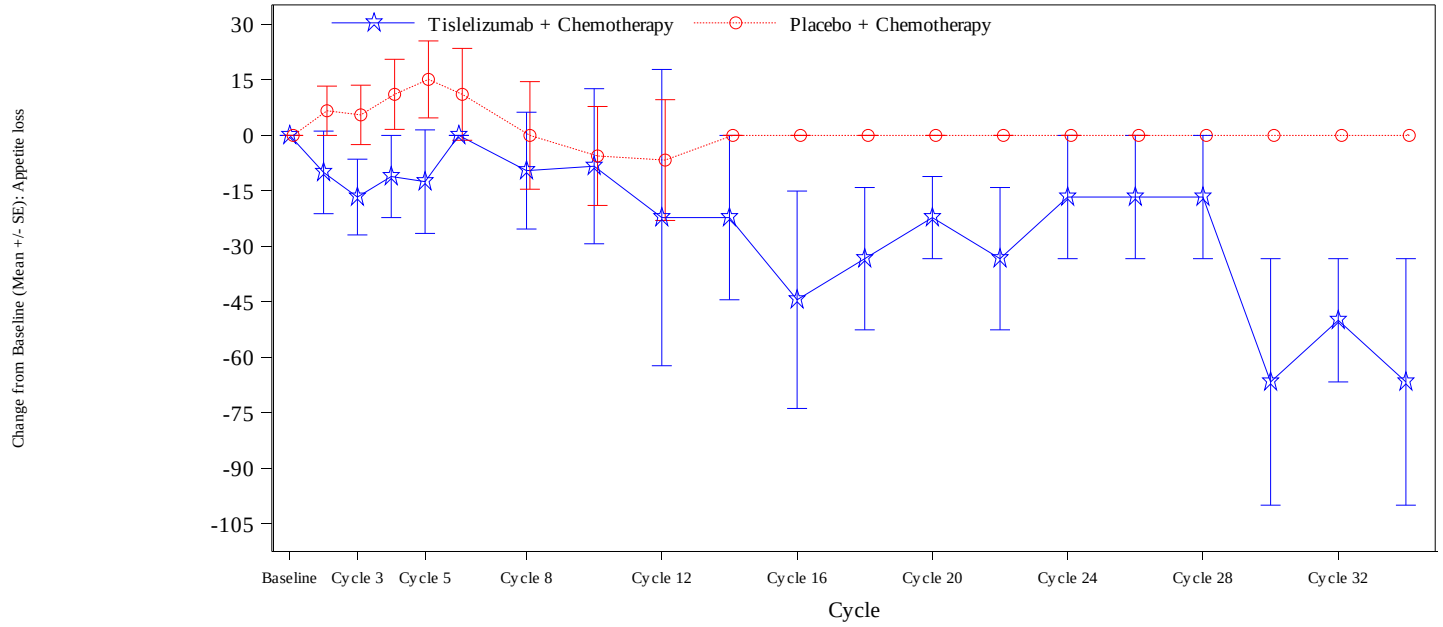

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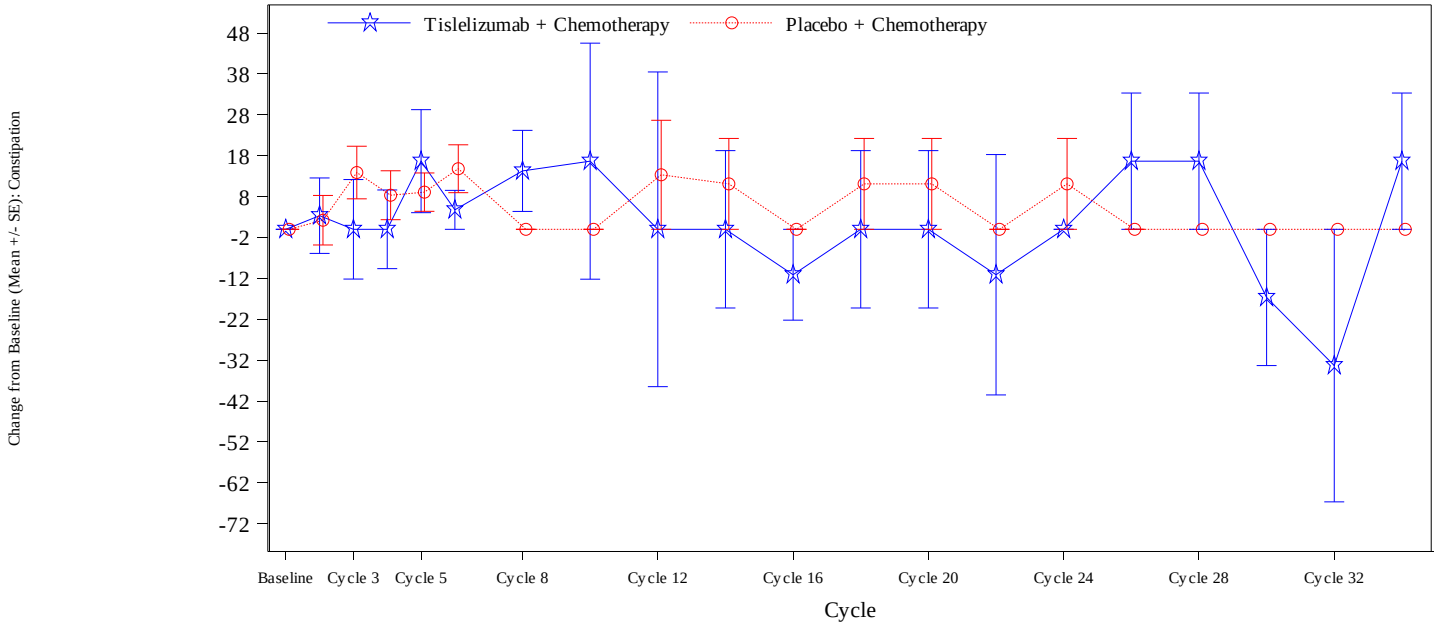

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ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

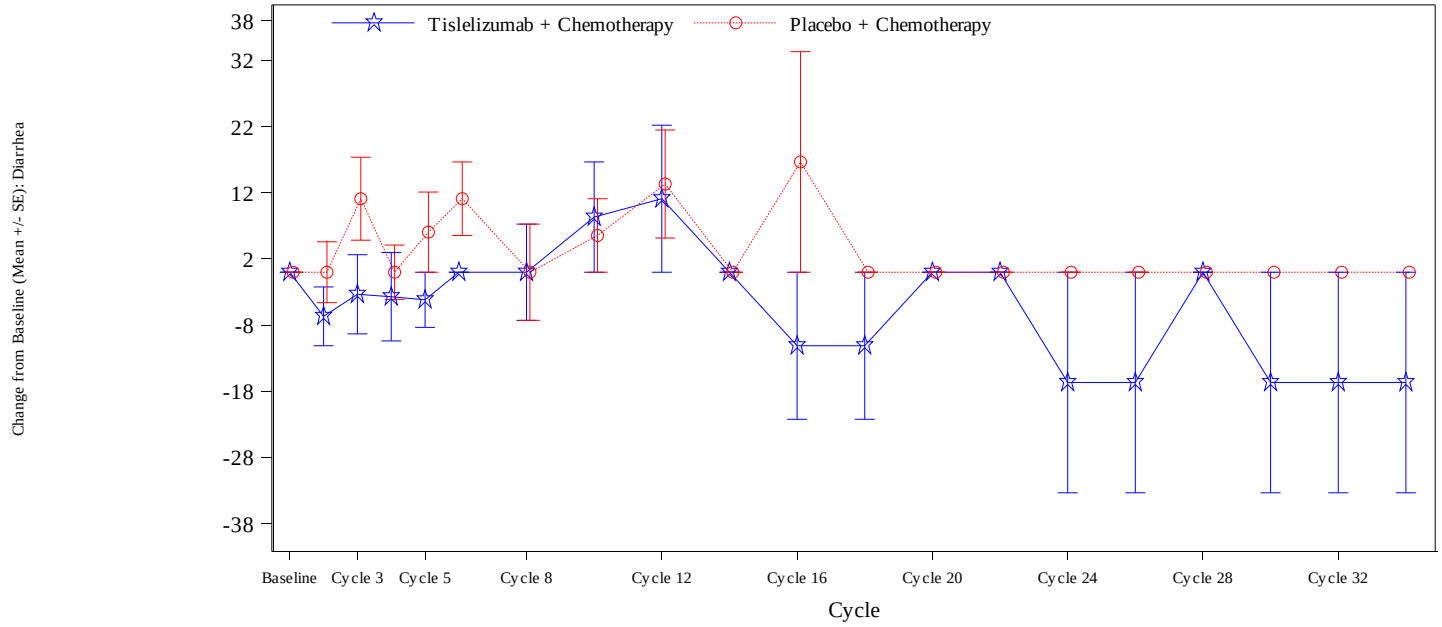

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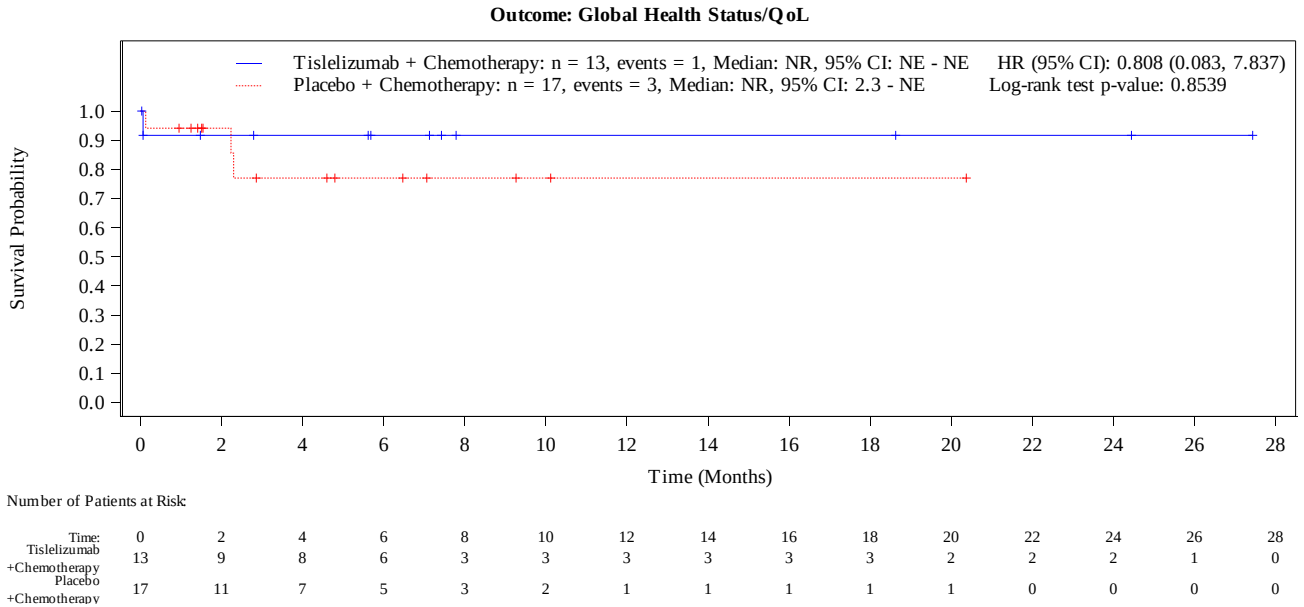
Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
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Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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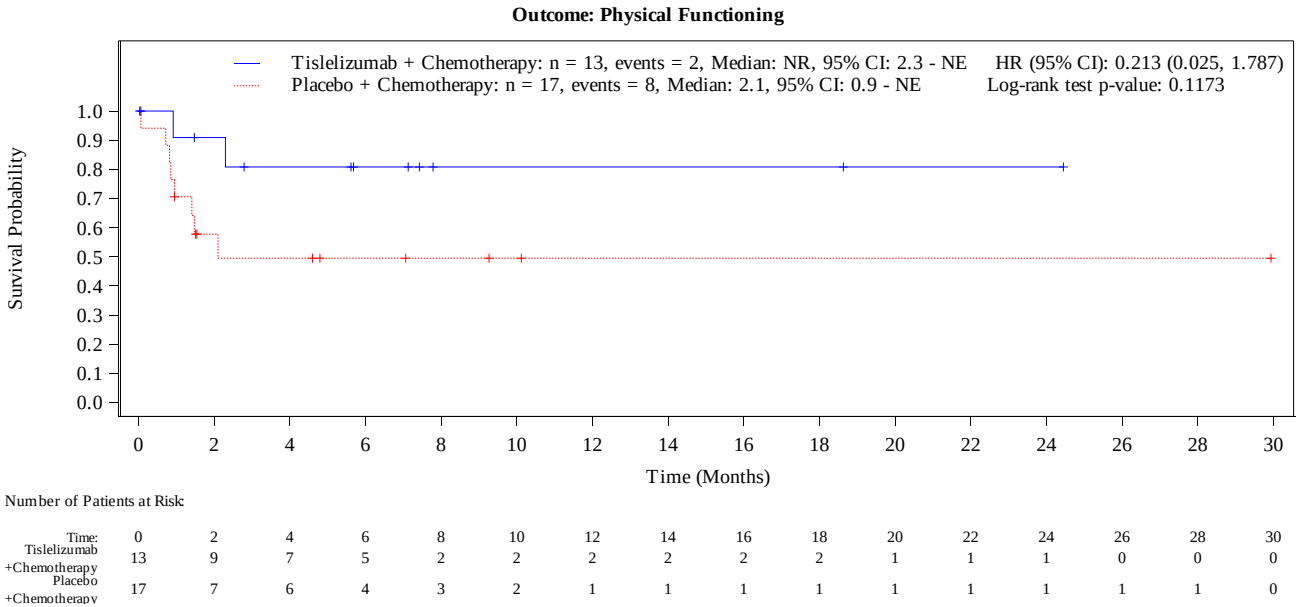

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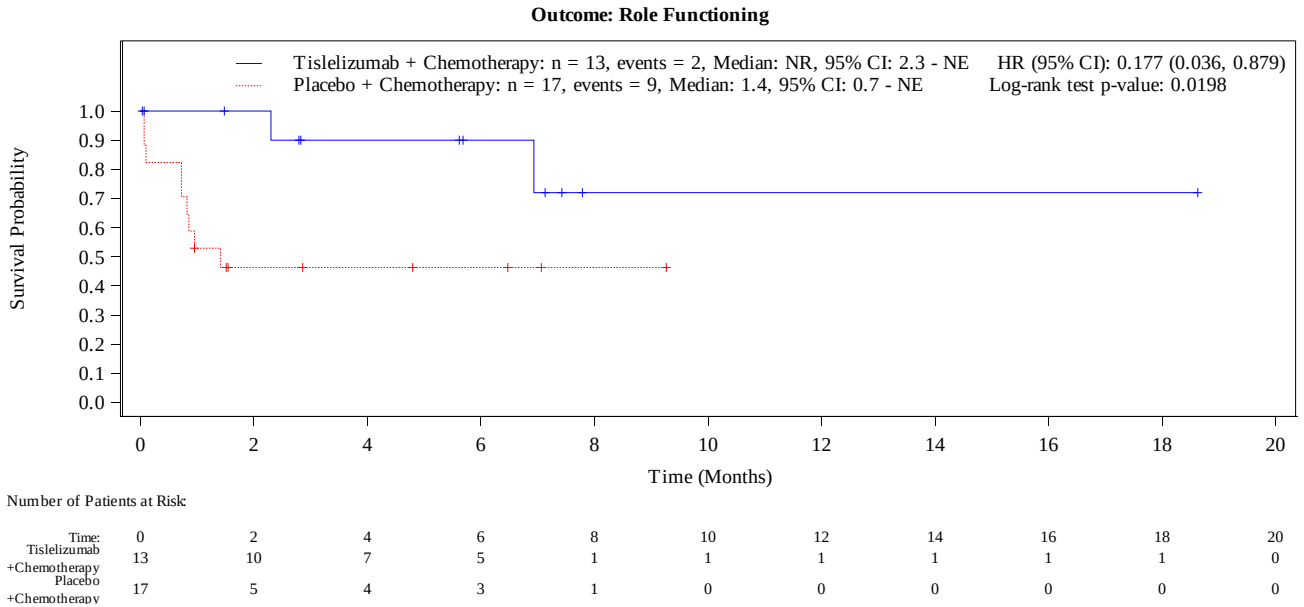

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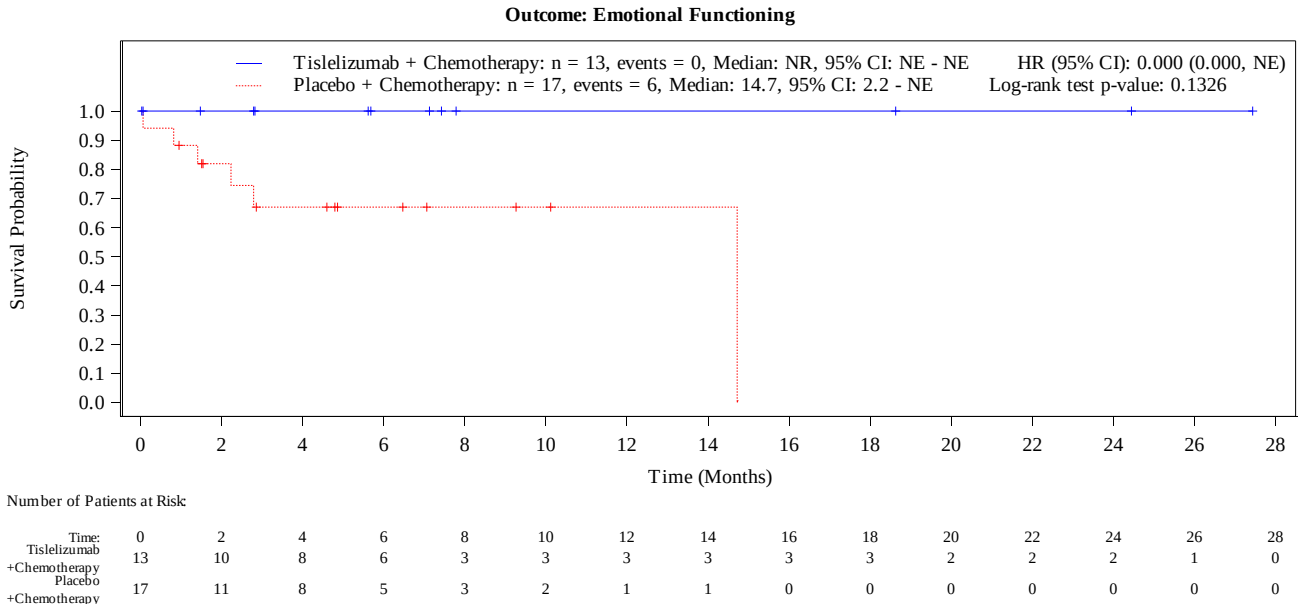

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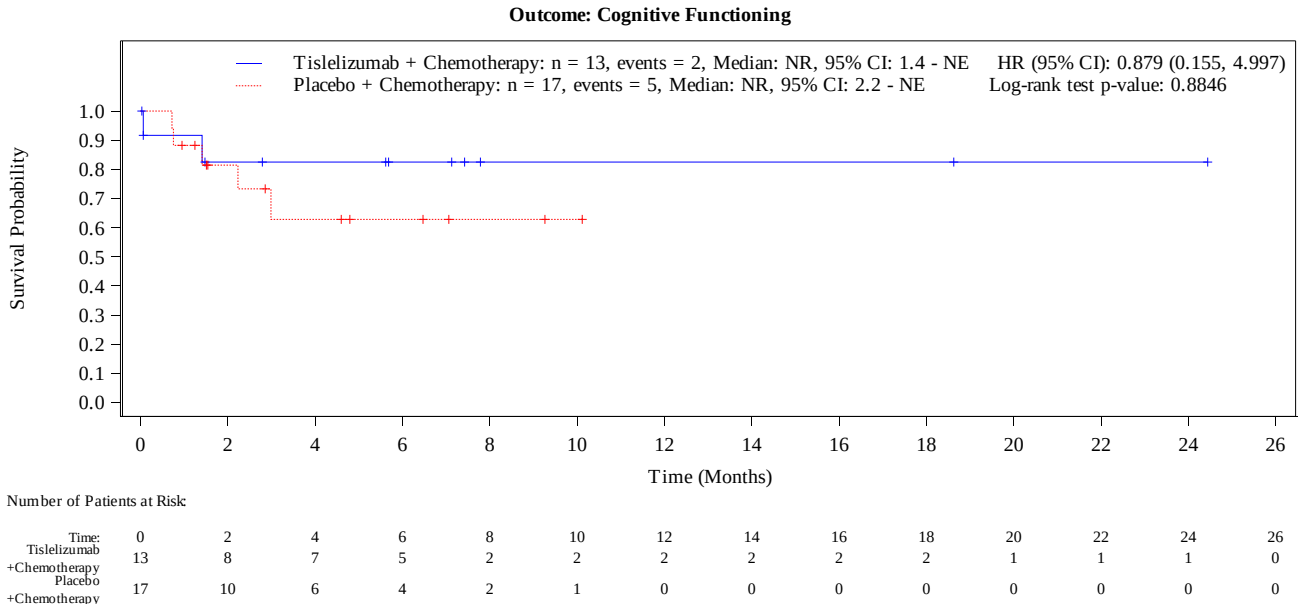

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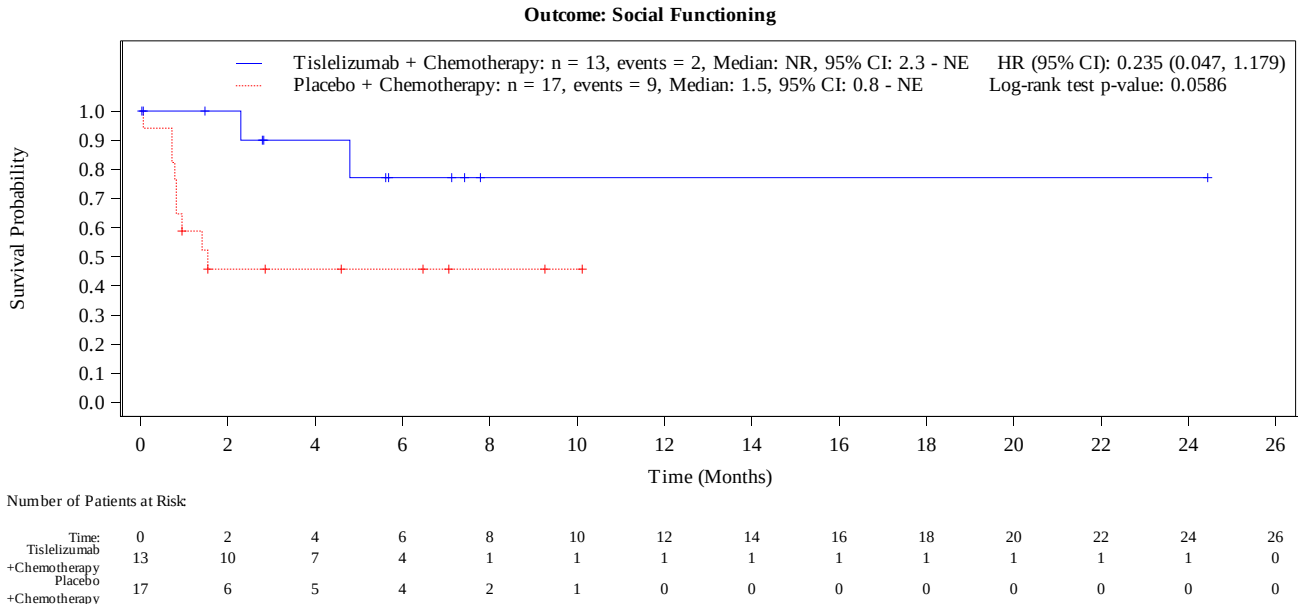

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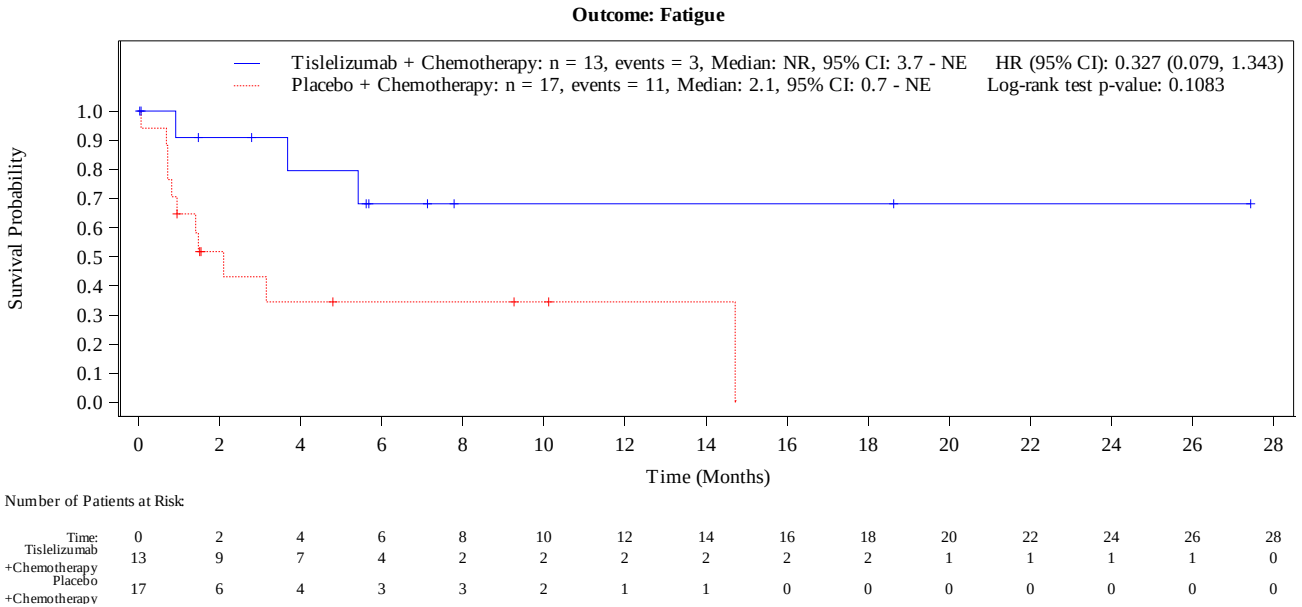

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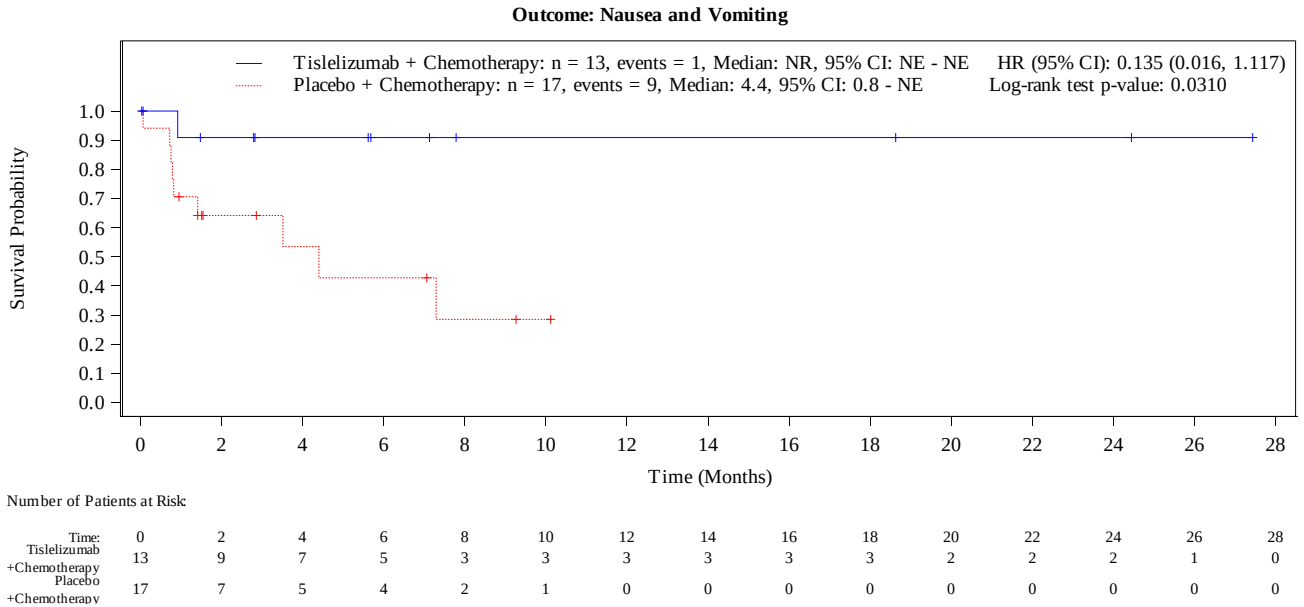
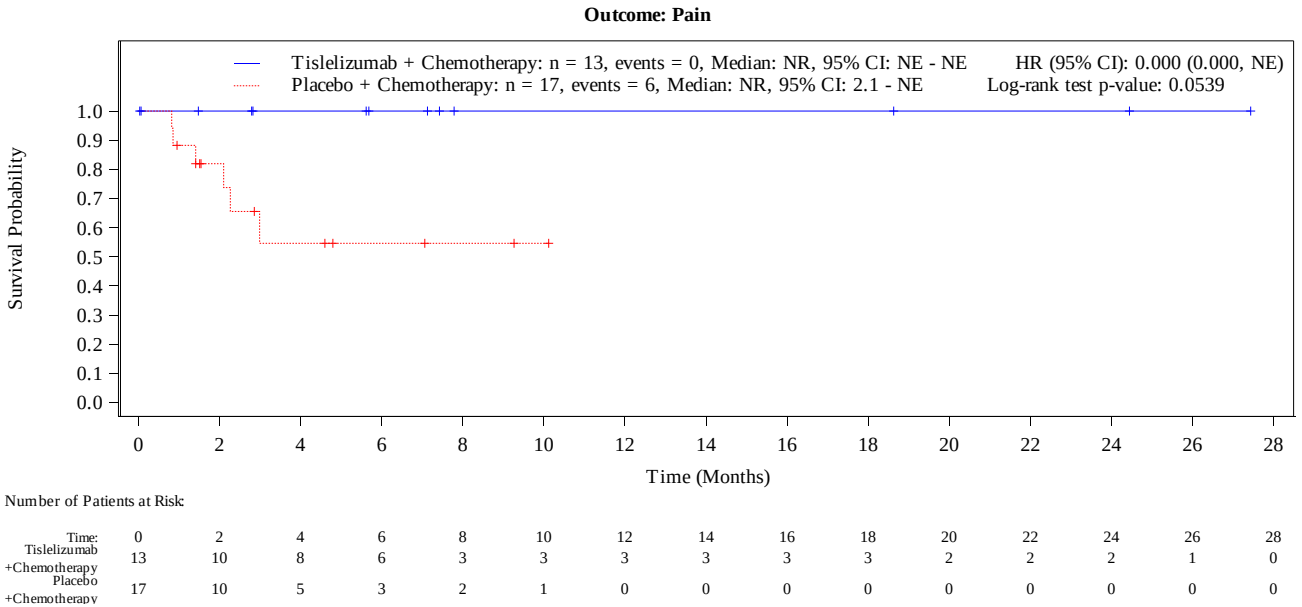
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



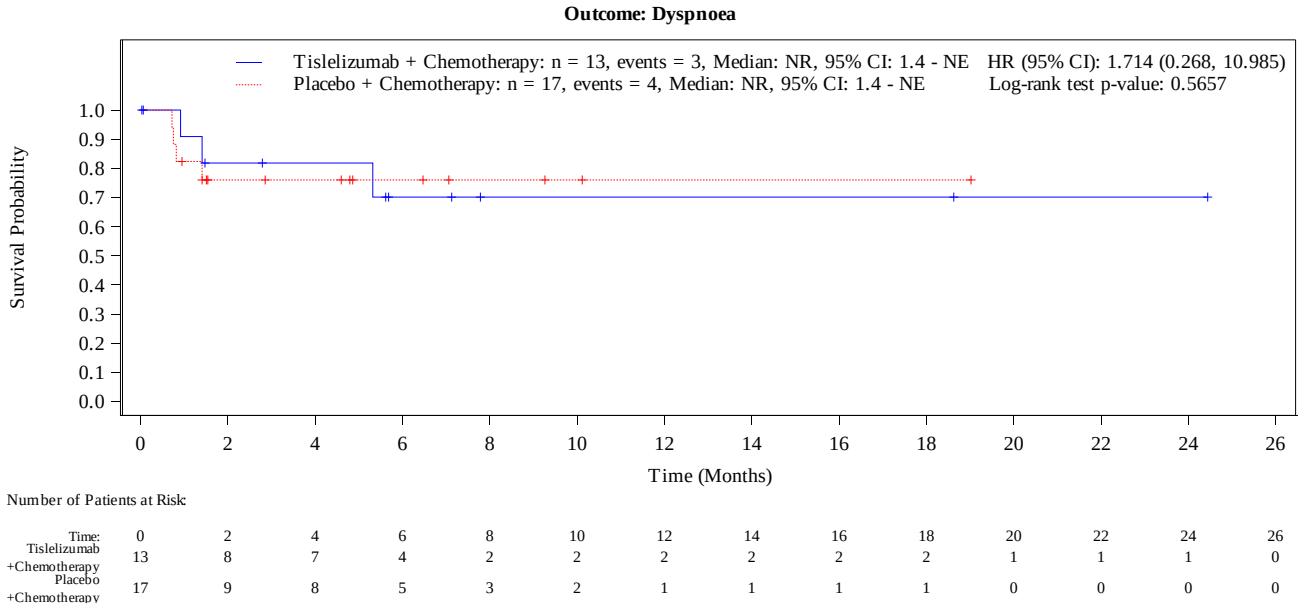
Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



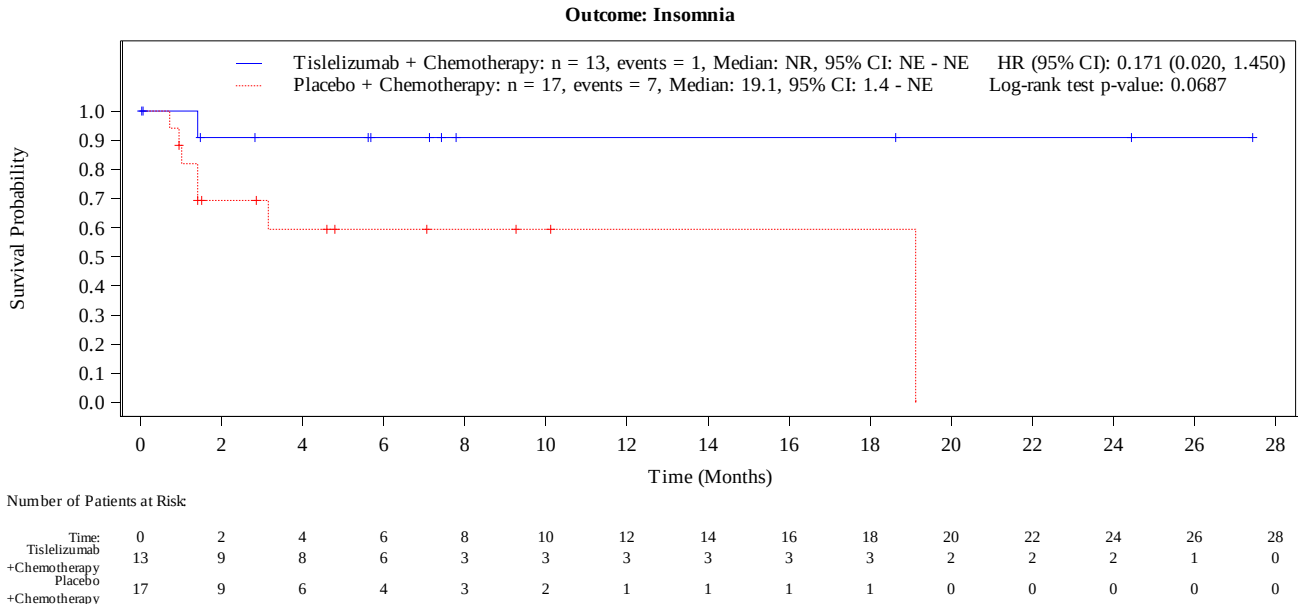
Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



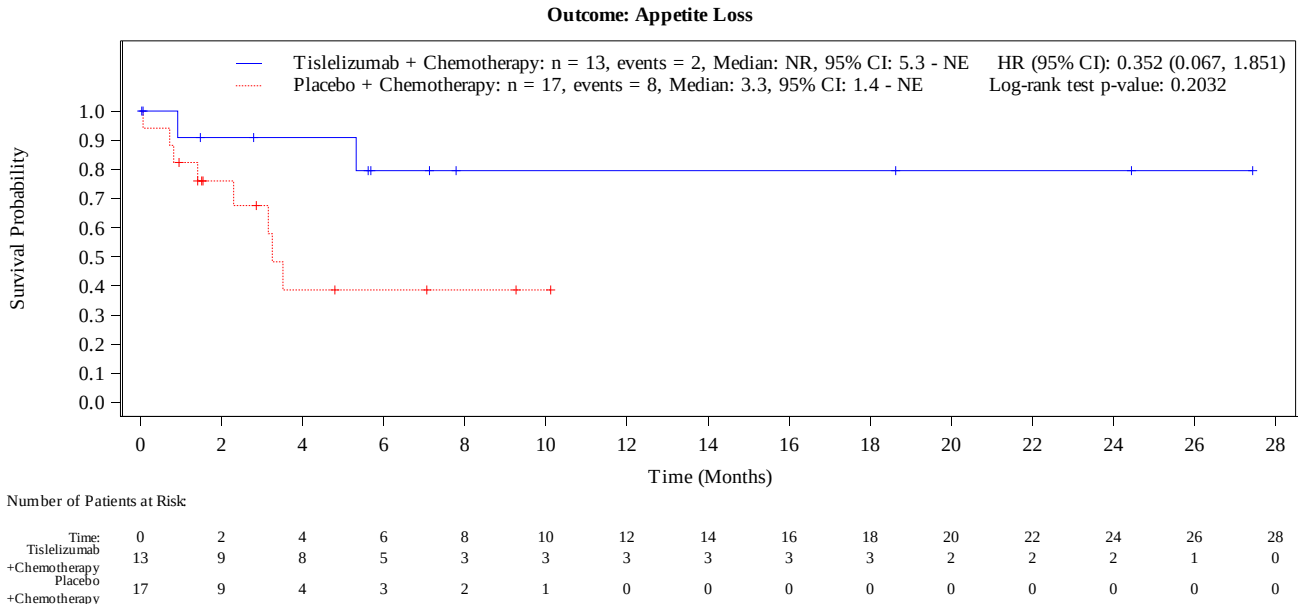
Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



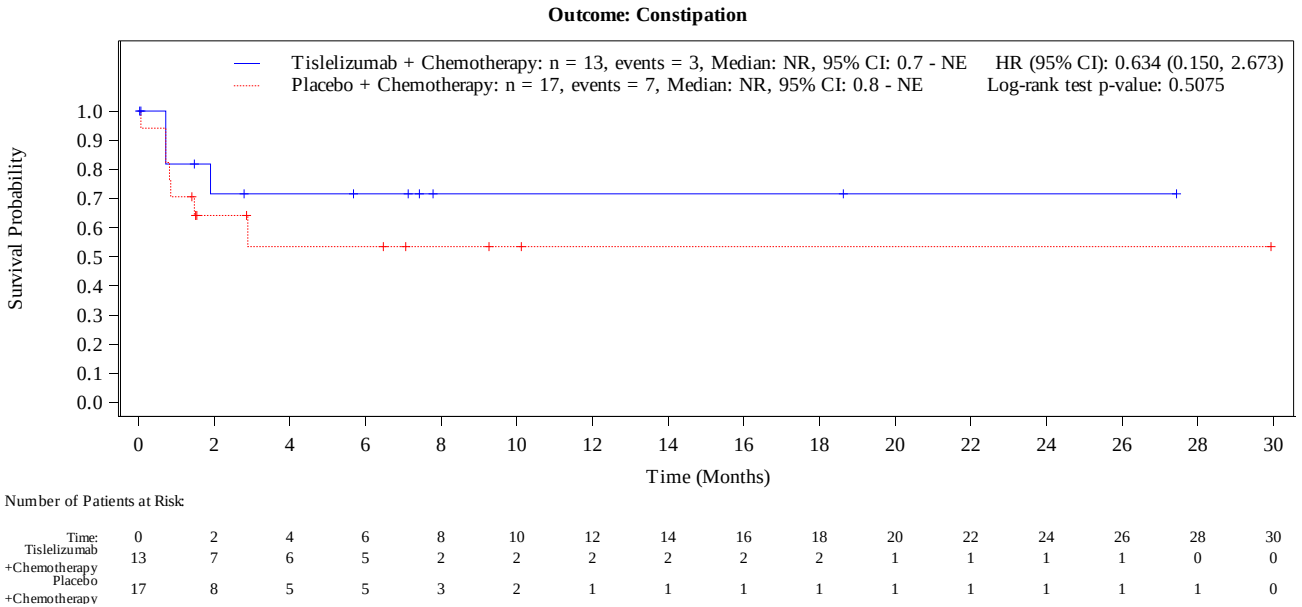
Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



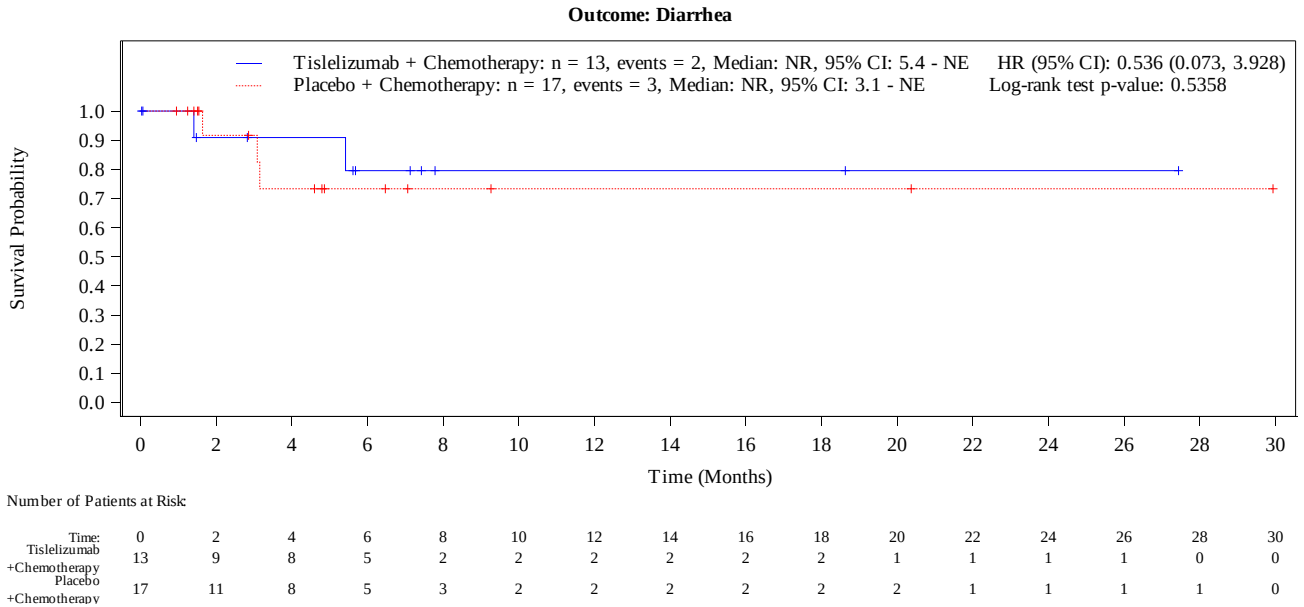
Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	6 (85.7)	--	--	--
No	9	0 (0.0)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	7 (63.6)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	3 (37.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	6 (75.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	7 (63.6)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	6 (60.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	7 (100.0)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	5 (83.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	2 (18.2)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

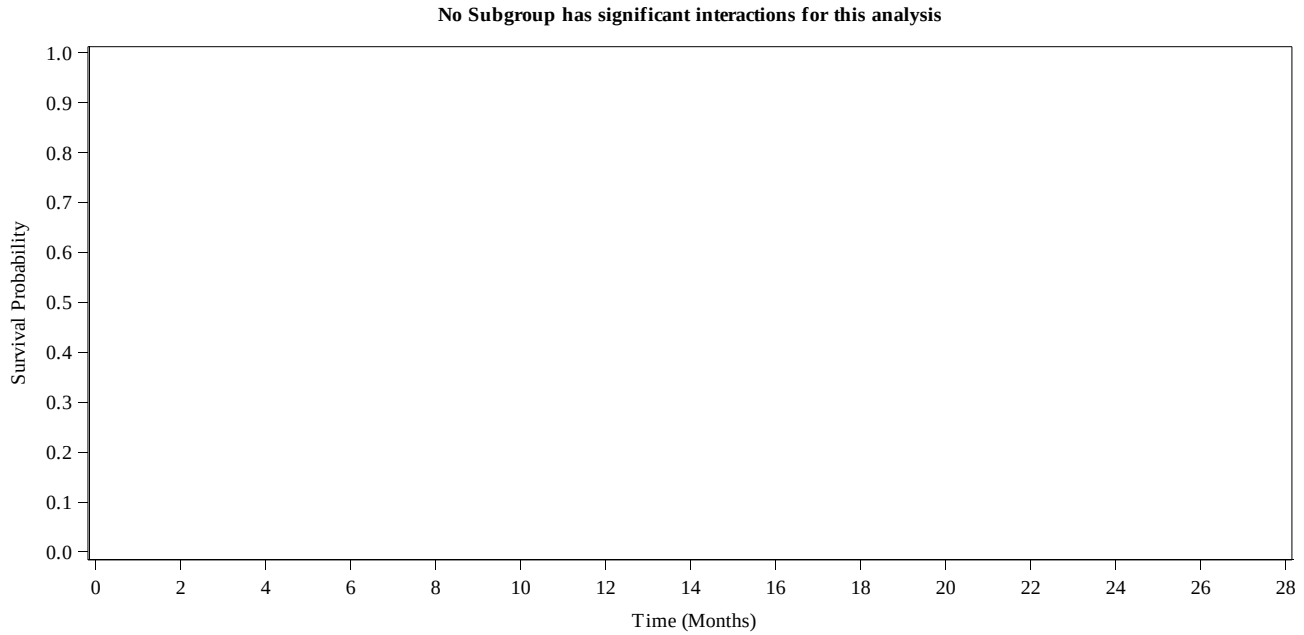
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-sa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-1-2-s-km-tteqs-subgrp-c30-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	53.7 (36.03)		58.2 (33.22)	
	Median	61.1		66.7	
	Q1, Q3	22.2, 83.3		33.3, 77.8	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	63.3 (40.25)	4.4 (19.74)	60.0 (34.32)	0.0 (34.12)
	Median	77.8	5.6	66.7	0.0
	Q1, Q3	11.1, 100.0	0.0, 11.1	33.3, 88.9	-33.3, 11.1
	Min, Max	0, 100	-33, 44	0, 100	-56, 78
Cycle 3	n	10	10	11	11
	Mean (SD)	56.7 (36.83)	-2.2 (15.54)	44.4 (39.13)	-18.2 (22.92)
	Median	66.7	0.0	55.6	-11.1
	Q1, Q3	22.2, 88.9	0.0, 0.0	0.0, 88.9	-33.3, 0.0
	Min, Max	0, 100	-33, 22	0, 100	-56, 11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	75.3 (35.91)	19.8 (33.69)	37.0 (37.41)	-20.4 (23.61)
	Median	88.9	11.1	38.9	-11.1
	Q1, Q3	66.7, 100.0	0.0, 22.2	0.0, 66.7	-33.3, 0.0
	Min, Max	0, 100	-22, 89	0, 100	-67, 0
Cycle 5	n	8	8	11	11
	Mean (SD)	62.5 (40.69)	9.7 (22.57)	49.5 (38.61)	-13.1 (26.68)
	Median	83.3	11.1	44.4	-11.1
	Q1, Q3	22.2, 94.4	0.0, 22.2	11.1, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 44	0, 100	-67, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	66.7 (40.57)	14.3 (19.99)	54.3 (40.61)	-6.2 (31.48)
	Median	77.8	11.1	66.7	0.0
	Q1, Q3	22.2, 100.0	0.0, 22.2	11.1, 77.8	-11.1, 0.0
	Min, Max	0, 100	0, 56	0, 100	-67, 44

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	65.1 (46.00)	14.3 (46.13)	39.7 (41.00)	-15.9 (23.88)
	Median	88.9	0.0	33.3	-11.1
	Q1, Q3	0.0, 100.0	0.0, 55.6	0.0, 88.9	-22.2, 0.0
	Min, Max	0, 100	-56, 89	0, 100	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	47.2 (44.79)	-8.3 (33.18)	48.1 (45.36)	-7.4 (41.38)
	Median	44.4	0.0	44.4	0.0
	Q1, Q3	11.1, 83.3	-27.8, 11.1	0.0, 100.0	-44.4, 22.2
	Min, Max	0, 100	-56, 22	0, 100	-67, 44
Cycle 12	n	3	3	5	5
	Mean (SD)	7.4 (12.83)	-44.4 (61.86)	60.0 (43.46)	-6.7 (44.17)
	Median	0.0	-55.6	66.7	0.0
	Q1, Q3	0.0, 22.2	-100.0, 22.2	33.3, 100.0	-33.3, 22.2
	Min, Max	0, 22	-100, 22	0, 100	-67, 44

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	63.0 (54.81)	11.1 (98.76)	63.0 (54.81)	-25.9 (35.72)
	Median	88.9	44.4	88.9	-11.1
	Q1, Q3	0.0, 100.0	-100.0, 88.9	0.0, 100.0	-66.7, 0.0
	Min, Max	0, 100	-100, 89	0, 100	-67, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	37.0 (54.81)	-14.8 (75.63)	33.3 (47.14)	-22.2 (15.71)
	Median	11.1	11.1	33.3	-22.2
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-33.3, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-33, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	40.7 (44.91)	-11.1 (94.93)	22.2 (38.49)	-37.0 (27.96)
	Median	33.3	-22.2	0.0	-33.3
	Q1, Q3	0.0, 88.9	-100.0, 88.9	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 89	-100, 89	0, 67	-67, -11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	-18.5 (73.98)	22.2 (38.49)	-37.0 (27.96)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-67, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-40.7 (52.51)	40.7 (39.02)	-18.5 (50.10)
	Median	0.0	-22.2	44.4	-22.2
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 77.8	-66.7, 33.3
	Min, Max	0, 33	-100, 0	0, 78	-67, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-33.3 (94.28)	22.2 (38.49)	-37.0 (27.96)
	Median	16.7	-33.3	0.0	-33.3
	Q1, Q3	0.0, 33.3	-100.0, 33.3	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 33	-100, 33	0, 67	-67, -11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	5.6 (7.86)	-33.3 (31.43)
	Median	0.0	-50.0	5.6	-33.3
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 11.1	-55.6, -11.1
	Min, Max	0, 0	-100, 0	0, 11	-56, -11
Cycle 28	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-44.4 (78.57)	0.0 (NE)	-11.1 (NE)
	Median	5.6	-44.4	0.0	-11.1
	Q1, Q3	0.0, 11.1	-100.0, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-100, 11	0, 0	-11, -11
Cycle 30	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-22.2 (47.14)	0.0 (NE)	-11.1 (NE)
	Median	5.6	-22.2	0.0	-11.1
	Q1, Q3	0.0, 11.1	-55.6, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-56, 11	0, 0	-11, -11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-22.2 (47.14)	0.0 (NE)	-11.1 (NE)
	Median	5.6	-22.2	0.0	-11.1
	Q1, Q3	0.0, 11.1	-55.6, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-56, 11	0, 0	-11, -11
Cycle 34	n	2	2	1	1
	Mean (SD)	44.4 (62.85)	16.7 (102.14)	0.0 (NE)	-11.1 (NE)
	Median	44.4	16.7	0.0	-11.1
	Q1, Q3	0.0, 88.9	-55.6, 88.9	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 89	-56, 89	0, 0	-11, -11
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 42	n	0	0	1	1
	Mean (SD)			22.2 (NE)	11.1 (NE)
	Median			22.2	11.1
	Q1, Q3			22.2, 22.2	11.1, 11.1
	Min, Max			22, 22	11, 11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			22.2 (NE)	11.1 (NE)
	Median			22.2	11.1
	Q1, Q3			22.2, 22.2	11.1, 11.1
	Min, Max			22, 22	11, 11
End of Treatment	n	9	9	14	14
	Mean (SD)	53.1 (41.86)	4.9 (17.67)	48.4 (34.76)	-9.5 (27.51)
	Median	66.7	0.0	55.6	0.0
	Q1, Q3	0.0, 88.9	0.0, 0.0	22.2, 66.7	-22.2, 11.1
	Min, Max	0, 100	-11, 44	0, 100	-56, 44

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	75.9 (38.73)	22.2 (31.43)	79.7 (21.60)	21.6 (23.40)
	Median	94.4	16.7	88.9	22.2
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	11.1, 33.3
	Min, Max	0, 100	-11, 100	33, 100	-22, 78

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	27.1 (30.18)		29.4 (24.32)	
	Median	25.0		16.7	
	Q1, Q3	0.0, 33.3		8.3, 41.7	
	Min, Max	0, 100		0, 75	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.0 (17.92)	-10.8 (32.64)	35.6 (26.81)	6.1 (16.20)
	Median	8.3	0.0	33.3	0.0
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 41.7	-8.3, 16.7
	Min, Max	0, 50	-100, 17	0, 100	-17, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	15.0 (16.57)	-10.8 (31.93)	32.6 (26.99)	-0.8 (18.80)
	Median	12.5	0.0	25.0	0.0
	Q1, Q3	0.0, 25.0	0.0, 0.0	16.7, 50.0	-8.3, 16.7
	Min, Max	0, 42	-100, 8	0, 92	-42, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (12.11)	-15.7 (33.71)	34.7 (25.58)	4.2 (18.97)
	Median	8.3	0.0	25.0	0.0
	Q1, Q3	0.0, 8.3	-16.7, 0.0	16.7, 58.3	-4.2, 12.5
	Min, Max	0, 33	-100, 8	0, 75	-25, 50
Cycle 5	n	8	8	11	11
	Mean (SD)	10.4 (10.68)	-14.6 (32.35)	31.8 (29.06)	5.3 (26.42)
	Median	8.3	0.0	25.0	8.3
	Q1, Q3	0.0, 20.8	-16.7, 0.0	0.0, 66.7	-16.7, 25.0
	Min, Max	0, 25	-92, 8	0, 67	-42, 50
Cycle 6	n	7	7	9	9
	Mean (SD)	13.1 (16.57)	-1.2 (7.50)	25.9 (23.73)	0.0 (22.44)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	8.3, 33.3	-8.3, 16.7
	Min, Max	0, 33	-17, 8	0, 67	-42, 25

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	-17.9 (37.40)	21.4 (24.47)	3.6 (27.58)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 50.0	-16.7, 25.0
	Min, Max	0, 33	-100, 8	0, 58	-42, 42
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (15.96)	-18.8 (43.23)	19.4 (36.77)	0.0 (34.56)
	Median	25.0	0.0	0.0	-8.3
	Q1, Q3	8.3, 33.3	-41.7, 4.2	0.0, 25.0	-16.7, 16.7
	Min, Max	0, 33	-83, 8	0, 92	-42, 58
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-33.3 (57.74)	16.7 (28.26)	-6.7 (27.26)
	Median	0.0	0.0	8.3	-8.3
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 8.3	-16.7, 0.0
	Min, Max	0, 33	-100, 0	0, 67	-42, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	2.8 (4.81)	-41.7 (46.40)	16.7 (22.05)	-5.6 (12.73)
	Median	0.0	-33.3	8.3	-8.3
	Q1, Q3	0.0, 8.3	-91.7, 0.0	0.0, 41.7	-16.7, 8.3
	Min, Max	0, 8	-92, 0	0, 42	-17, 8
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-38.9 (41.94)	20.8 (29.46)	0.0 (11.79)
	Median	0.0	-33.3	20.8	0.0
	Q1, Q3	0.0, 16.7	-83.3, 0.0	0.0, 41.7	-8.3, 8.3
	Min, Max	0, 17	-83, 0	0, 42	-8, 8
Cycle 18	n	3	3	3	3
	Mean (SD)	19.4 (17.35)	-25.0 (43.30)	16.7 (16.67)	-2.8 (12.73)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-75.0, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-75, 0	0, 33	-17, 8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	16.7 (16.67)	-2.8 (12.73)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-67, 0	0, 33	-17, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	22.2 (19.25)	2.8 (20.97)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 25.0
	Min, Max	0, 33	-67, 0	0, 33	-17, 25
Cycle 24	n	2	2	3	3
	Mean (SD)	8.3 (11.79)	-8.3 (11.79)	19.4 (12.73)	0.0 (8.33)
	Median	8.3	-8.3	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	8.3, 33.3	-8.3, 8.3
	Min, Max	0, 17	-17, 0	8, 33	-8, 8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	12.5 (17.68)	-4.2 (5.89)	16.7 (0.00)	4.2 (5.89)
	Median	12.5	-4.2	16.7	4.2
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 16.7	0.0, 8.3
	Min, Max	0, 25	-8, 0	17, 17	0, 8
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	25.0 (NE)	16.7 (NE)
	Median	16.7	0.0	25.0	16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	25.0, 25.0	16.7, 16.7
	Min, Max	0, 33	0, 0	25, 25	17, 17
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-50.0 (70.71)	0.0 (NE)	-8.3 (NE)
	Median	16.7	-50.0	0.0	-8.3
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 0.0	-8.3, -8.3
	Min, Max	0, 33	-100, 0	0, 0	-8, -8

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	29.2 (5.89)	-37.5 (53.03)	8.3 (NE)	0.0 (NE)
	Median	29.2	-37.5	8.3	0.0
	Q1, Q3	25.0, 33.3	-75.0, 0.0	8.3, 8.3	0.0, 0.0
	Min, Max	25, 33	-75, 0	8, 8	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	12.5 (17.68)	-54.2 (29.46)	16.7 (NE)	8.3 (NE)
	Median	12.5	-54.2	16.7	8.3
	Q1, Q3	0.0, 25.0	-75.0, -33.3	16.7, 16.7	8.3, 8.3
	Min, Max	0, 25	-75, -33	17, 17	8, 8
Cycle 36	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			16.7 (NE)	8.3 (NE)
	Median			16.7	8.3
	Q1, Q3			16.7, 16.7	8.3, 8.3
	Min, Max			17, 17	8, 8
Cycle 42	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	25.0 (NE)
	Median			33.3	25.0
	Q1, Q3			33.3, 33.3	25.0, 25.0
	Min, Max			33, 33	25, 25
End of Treatment	n	9	9	14	14
	Mean (SD)	16.7 (15.59)	-0.9 (16.37)	41.7 (28.68)	10.1 (26.79)
	Median	16.7	0.0	41.7	0.0
	Q1, Q3	0.0, 25.0	-8.3, 8.3	16.7, 58.3	0.0, 33.3
	Min, Max	0, 42	-33, 17	0, 83	-42, 58

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	31.9 (26.07)	4.9 (24.99)	56.4 (25.94)	27.0 (20.10)
	Median	33.3	8.3	50.0	25.0
	Q1, Q3	8.3, 50.0	0.0, 16.7	41.7, 66.7	16.7, 41.7
	Min, Max	0, 83	-67, 33	17, 100	-8, 58

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	4.2 (10.36)		12.7 (20.01)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 16.7	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (10.54)	14.4 (17.67)	3.3 (9.34)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 50	-17, 17
Cycle 3	n	10	10	11	11
	Mean (SD)	5.0 (11.25)	0.0 (7.86)	18.2 (17.41)	4.5 (16.82)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 17	0, 50	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	0.0 (0.00)	-5.6 (11.79)	13.9 (18.58)	1.4 (16.60)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 8.3
	Min, Max	0, 0	-33, 0	0, 50	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	2.1 (5.89)	-4.2 (7.72)	13.6 (17.98)	1.5 (17.41)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-8.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	0, 50	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	16.7 (16.67)	1.9 (22.74)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 50	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (0.00)	9.5 (16.27)	0.0 (21.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 33	0, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (20.97)	8.3 (9.62)	5.6 (13.61)	-5.6 (17.21)
	Median	16.7	8.3	0.0	0.0
	Q1, Q3	8.3, 33.3	0.0, 16.7	0.0, 0.0	-16.7, 0.0
	Min, Max	0, 50	0, 17	0, 33	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	6.7 (9.13)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	25.0 (11.79)	8.3 (11.79)
	Median	0.0	-16.7	25.0	8.3
	Q1, Q3	0.0, 16.7	-16.7, 0.0	16.7, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	17, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	22.2 (19.25)	11.1 (9.62)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 33	0, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	5.6 (9.62)	-5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	-16.7, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (9.62)	-5.6 (9.62)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 17	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (0.00)	-8.3 (11.79)
	Median	0.0	-16.7	0.0	-8.3
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	-16.7, 0.0
	Min, Max	0, 0	-33, 0	0, 0	-17, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	0.0 (NE)	-16.7 (NE)
	Median	0.0	-16.7	0.0	-16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	0, 0	-33, 0	0, 0	-17, -17
Cycle 30	n	2	2	1	1
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	0.0 (NE)	-16.7 (NE)
	Median	25.0	0.0	0.0	-16.7
	Q1, Q3	16.7, 33.3	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	17, 33	0, 0	0, 0	-17, -17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	0.0 (NE)	-16.7 (NE)
	Median	25.0	0.0	0.0	-16.7
	Q1, Q3	16.7, 33.3	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	17, 33	0, 0	0, 0	-17, -17
Cycle 34	n	2	2	1	1
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	16.7 (NE)	0.0 (NE)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	16.7, 33.3	0.0, 0.0	16.7, 16.7	0.0, 0.0
	Min, Max	17, 33	0, 0	17, 17	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-16.7 (NE)
	Median			0.0	-16.7
	Q1, Q3			0.0, 0.0	-16.7, -16.7
	Min, Max			0, 0	-17, -17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			16.7 (NE)	0.0 (NE)
	Median			16.7	0.0
	Q1, Q3			16.7, 16.7	0.0, 0.0
	Min, Max			17, 17	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	5.6 (8.33)	1.9 (15.47)	15.5 (16.62)	2.4 (20.52)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 17	-33, 17	0, 33	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	12.5 (16.09)	8.3 (11.24)	28.4 (18.41)	15.7 (16.11)
	Median	8.3	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 16.7	16.7, 50.0	0.0, 33.3
	Min, Max	0, 50	0, 33	0, 50	-17, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	12.0 (18.02)		22.9 (20.21)	
	Median	0.0		22.2	
	Q1, Q3	0.0, 22.2		11.1, 33.3	
	Min, Max	0, 56		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.5 (21.61)	-1.5 (15.64)
	Median	0.0	0.0	22.2	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 22	-33, 11	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.2 (23.55)	-4.0 (15.13)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 0.0
	Min, Max	0, 22	-33, 11	0, 67	-33, 22

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (7.86)	-9.9 (15.16)	14.8 (18.55)	-8.3 (15.08)
	Median	0.0	0.0	5.6	-5.6
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 27.8	-16.7, 0.0
	Min, Max	0, 22	-33, 0	0, 56	-33, 11
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	-8.3 (12.94)	17.2 (25.99)	-3.0 (20.54)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 0	-33, 0	0, 89	-33, 44
Cycle 6	n	7	7	9	9
	Mean (SD)	1.6 (4.20)	-3.2 (10.57)	16.0 (21.60)	-2.5 (17.37)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-11.1, 0.0	0.0, 11.1	-11.1, 11.1
	Min, Max	0, 11	-22, 11	0, 67	-33, 22

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.74)	-4.8 (10.84)	7.9 (12.36)	-4.8 (14.14)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (10.64)	-5.6 (14.34)	7.4 (13.46)	-5.6 (15.32)
	Median	5.6	-5.6	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 5.6	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (11.11)	-7.4 (12.83)	6.7 (14.91)	-8.9 (14.49)
	Median	11.1	0.0	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, 0.0	0.0, 0.0	-11.1, 0.0
	Min, Max	0, 22	-22, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	14.8 (16.97)	0.0 (11.11)
	Median	0.0	-22.2	11.1	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 0	-33, 0	0, 33	-11, 11
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-22.2	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	3.7 (6.42)	-14.8 (12.83)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 11	-22, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	3.7 (27.96)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-22.2, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-22, 33	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	14.8 (16.97)	3.7 (6.42)
	Median	0.0	-11.1	11.1	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 11.1
	Min, Max	0, 0	-22, 0	0, 33	0, 11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	0.0 (NE)	0.0 (NE)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	11.1 (0.00)	-16.7 (7.86)	0.0 (NE)	0.0 (NE)
	Median	11.1	-16.7	0.0	0.0
	Q1, Q3	11.1, 11.1	-22.2, -11.1	0.0, 0.0	0.0, 0.0
	Min, Max	11, 11	-22, -11	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	5.6 (7.86)	-22.2 (0.00)	0.0 (NE)	0.0 (NE)
	Median	5.6	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, -22.2	0.0, 0.0	0.0, 0.0
	Min, Max	0, 11	-22, -22	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	11.1 (15.71)	-16.7 (7.86)	0.0 (NE)	0.0 (NE)
	Median	11.1	-16.7	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, -11.1	0.0, 0.0	0.0, 0.0
	Min, Max	0, 22	-22, -11	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			11.1 (NE)	11.1 (NE)
	Median			11.1	11.1
	Q1, Q3			11.1, 11.1	11.1, 11.1
	Min, Max			11, 11	11, 11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			11.1 (NE)	11.1 (NE)
	Median			11.1	11.1
	Q1, Q3			11.1, 11.1	11.1, 11.1
	Min, Max			11, 11	11, 11
End of Treatment	n	9	9	14	14
	Mean (SD)	6.2 (11.26)	-3.7 (21.52)	23.8 (24.21)	0.8 (21.11)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 44.4	-11.1, 11.1
	Min, Max	0, 33	-44, 33	0, 67	-33, 44

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	20.4 (29.52)	8.3 (17.81)	35.9 (24.70)	13.1 (16.31)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	0.0, 27.8	11.1, 44.4	0.0, 22.2
	Min, Max	0, 89	-22, 33	0, 89	0, 44

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		17.6 (33.58)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	17.8 (24.77)	0.0 (41.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	-100, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	21.2 (37.34)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	25.0 (40.51)	2.8 (43.71)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 50.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	12.1 (22.47)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	-100, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (33.33)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 100	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.3 (37.80)	0.0 (57.74)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (57.74)	33.3 (57.74)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 100.0	0.0, 100.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	44.4 (50.92)	44.4 (50.92)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 0	0, 0	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	14.8 (33.79)	14.8 (33.79)	42.9 (37.96)	23.8 (30.46)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	33.3 (34.82)	33.3 (34.82)	56.9 (36.83)	39.2 (35.81)
	Median	33.3	33.3	66.7	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 100.0	0.0, 66.7
	Min, Max	0, 100	0, 100	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		9.8 (15.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (30.63)	17.8 (17.21)	6.7 (18.69)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	0.0 (0.00)	-13.3 (23.31)	24.2 (33.63)	18.2 (34.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-67, 0	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-11.1 (28.87)	19.4 (30.01)	13.9 (30.01)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 100	0, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (17.25)	-4.2 (27.82)	15.2 (22.92)	9.1 (21.56)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	9.5 (16.27)	0.0 (0.00)	11.1 (16.67)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-14.3 (32.53)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (27.22)	11.1 (17.21)	5.6 (13.61)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 16.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	6.7 (14.91)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (0.00)	-11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 0	-67, 0	0, 0	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	7.4 (14.70)	0.0 (23.57)	28.6 (28.81)	19.0 (31.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	19.4 (17.16)	5.6 (23.92)	35.3 (24.92)	25.5 (30.11)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		15.7 (29.15)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	6.7 (21.08)	31.1 (29.46)	13.3 (24.56)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	20.0 (17.21)	3.3 (24.60)	27.3 (29.13)	12.1 (16.82)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	25.9 (22.22)	7.4 (14.70)	30.6 (30.01)	16.7 (22.47)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	16.7 (25.20)	0.0 (17.82)	24.2 (26.21)	18.2 (22.92)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	19.0 (26.23)	9.5 (25.20)	25.9 (22.22)	18.5 (17.57)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (17.82)	0.0 (19.25)	9.5 (16.27)	4.8 (12.60)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (47.14)	16.7 (27.89)	11.1 (17.21)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-67, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	0.0 (33.33)	20.0 (18.26)	13.3 (18.26)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	50.0 (23.57)	33.3 (0.00)
	Median	0.0	0.0	50.0	33.3
	Q1, Q3	0.0, 33.3	-66.7, 0.0	33.3, 66.7	33.3, 33.3
	Min, Max	0, 33	-67, 0	33, 67	33, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	33.3 (33.33)	22.2 (38.49)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-67, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	44.4 (50.92)	33.3 (57.74)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	0.0 (0.00)	33.3 (33.33)	22.2 (38.49)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 67	0, 0	0, 67	0, 67
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (47.14)	22.2 (19.25)	11.1 (19.25)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	33.3 (47.14)	33.3 (47.14)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-33, 0	0, 67	0, 67
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	66.7 (NE)	66.7 (NE)
	Median	0.0	-16.7	66.7	66.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	66.7, 66.7	66.7, 66.7
	Min, Max	0, 0	-33, 0	67, 67	67, 67
Cycle 30	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-33.3 (0.00)	33.3 (NE)	33.3 (NE)
	Median	16.7	-33.3	33.3	33.3
	Q1, Q3	0.0, 33.3	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	0, 33	-33, -33	33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	33.3 (47.14)	-16.7 (23.57)	33.3 (NE)	33.3 (NE)
	Median	33.3	-16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	-33.3, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 67	-33, 0	33, 33	33, 33
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-33.3 (0.00)	66.7 (NE)	66.7 (NE)
	Median	16.7	-33.3	66.7	66.7
	Q1, Q3	0.0, 33.3	-33.3, -33.3	66.7, 66.7	66.7, 66.7
	Min, Max	0, 33	-33, -33	67, 67	67, 67
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	14.8 (17.57)	3.7 (30.93)	33.3 (36.98)	16.7 (31.35)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	47.2 (22.29)	25.0 (20.72)	49.0 (33.58)	33.3 (31.18)
	Median	33.3	33.3	33.3	33.3
	Q1, Q3	33.3, 66.7	33.3, 33.3	33.3, 66.7	0.0, 66.7
	Min, Max	33, 100	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	11.1 (29.59)		9.8 (19.60)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 0.0	
	Min, Max	0, 100		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	24.4 (29.46)	13.3 (24.56)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	27.3 (35.96)	15.2 (37.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (26.06)	30.6 (36.12)	19.4 (26.43)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 100	0, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (24.80)	0.0 (17.82)	27.3 (29.13)	21.2 (30.81)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	37.0 (35.14)	33.3 (33.33)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (25.20)	23.8 (37.09)	19.0 (37.80)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (27.22)	16.7 (40.82)	11.1 (27.22)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (19.25)	-11.1 (50.92)	20.0 (29.81)	13.3 (18.26)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	0.0 (NE)	0.0 (NE)
	Median	0.0	-50.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	50.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	50.0 (70.71)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	50.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	28.6 (36.65)	21.4 (30.96)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	16.7 (30.15)	5.6 (19.25)	51.0 (37.49)	41.2 (32.34)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 16.7	33.3, 100.0	33.3, 66.7
	Min, Max	0, 100	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	2.8 (9.62)		13.7 (23.74)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	13.3 (21.08)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	15.2 (22.92)	0.0 (25.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	7.4 (14.70)	19.4 (26.43)	5.6 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	4.2 (11.79)	15.2 (22.92)	6.1 (25.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	11.1 (23.57)	0.0 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	16.7 (40.82)	11.1 (27.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (NE)	0.0 (NE)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
End of Treatment	n	9	9	14	14
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	26.2 (29.75)	11.9 (28.06)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	13.9 (17.16)	11.1 (21.71)	39.2 (33.82)	25.5 (27.71)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	8.3 (15.08)		15.7 (23.91)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 16.7		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (14.05)	20.0 (27.60)	4.4 (27.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	-3.3 (10.54)	18.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-7.4 (14.70)	19.4 (30.01)	2.8 (22.29)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 100	-33, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-8.3 (15.43)	21.2 (26.97)	6.1 (32.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	-4.8 (12.60)	11.1 (16.67)	-7.4 (22.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (16.27)	9.5 (16.27)	-9.5 (25.20)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (0.00)	11.1 (27.22)	-11.1 (34.43)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	6.7 (14.91)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	16.7 (23.57)	-16.7 (23.57)
	Median	0.0	-33.3	16.7	-16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)	-16.7 (23.57)
	Median	16.7	0.0	0.0	-16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 0	-33, 0
Cycle 28	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	0.0 (NE)	-33.3 (NE)
	Median	16.7	0.0	0.0	-33.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	0, 0	0, 0	-33, -33
Cycle 30	n	2	2	1	1
	Mean (SD)	0.0 (0.00)	-33.3 (0.00)	0.0 (NE)	-33.3 (NE)
	Median	0.0	-33.3	0.0	-33.3
	Q1, Q3	0.0, 0.0	-33.3, -33.3	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 0	-33, -33	0, 0	-33, -33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	0.0 (NE)	-33.3 (NE)
	Median	16.7	-16.7	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 34	n	2	2	1	1
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	0.0 (NE)	-33.3 (NE)
	Median	16.7	-16.7	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 36	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-33.3 (NE)
	Median			0.0	-33.3
	Q1, Q3			0.0, 0.0	-33.3, -33.3
	Min, Max			0, 0	-33, -33
Cycle 42	n	0	0	1	1
	Mean (SD)			66.7 (NE)	33.3 (NE)
	Median			66.7	33.3
	Q1, Q3			66.7, 66.7	33.3, 33.3
	Min, Max			67, 67	33, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
End of Treatment	n	9	9	14	14
	Mean (SD)	0.0 (0.00)	-7.4 (14.70)	14.3 (21.54)	0.0 (26.15)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 67	-67, 33

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	5.6 (12.97)	-2.8 (9.62)	39.2 (35.81)	23.5 (28.30)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 100	-33, 67

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	53.70 (36.03)	-8.93 (6.75)	17	58.17 (33.22)	-12.75 (5.13)	3.82 (-11.92, 19.56)	0.21 (-0.64, 1.06)	0.6191

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Eating									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	27.08 (30.18)	-11.10 (6.84)	17	29.41 (24.32)	3.42 (5.04)	-14.52 (-30.47, 1.44)	-0.75 (-1.59, 0.09)	0.0723

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Reflux									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	4.17 (10.36)	-3.87 (2.35)	17	12.75 (20.01)	4.72 (1.91)	-8.58 (-14.10, -3.06)	-1.52 (-2.56, -0.48)	0.0036

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain (OES18)									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	12.04 (18.02)	-8.04 (3.89)	17	22.88 (20.21)	-0.52 (3.02)	-7.52 (-16.84, 1.80)	-0.73 (-1.63, 0.18)	0.1083

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble swallowing saliva									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	-1.67 (6.34)	17	17.65 (33.58)	5.04 (5.07)	-6.71 (-21.97, 8.55)	-0.39 (-1.27, 0.49)	0.3700

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Choked when swallowing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-8.65 (5.46)	17	9.80 (15.66)	9.96 (4.07)	-18.61 (-31.24, -5.97)	-1.30 (-2.25, -0.35)	0.0060

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dry mouth									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	7.19 (5.42)	17	15.69 (29.15)	13.10 (4.12)	-5.91 (-18.43, 6.62)	-0.42 (-1.31, 0.46)	0.3397

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with taste									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	11.11 (29.59)	-12.08 (7.60)	17	9.80 (19.60)	9.77 (5.46)	-21.84 (-38.98, -4.70)	-1.08 (-1.97, -0.19)	0.0149

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with coughing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	2.78 (9.62)	-0.18 (5.25)	17	13.73 (23.74)	4.28 (3.89)	-4.46 (-17.06, 8.14)	-0.32 (-1.20, 0.57)	0.4723

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

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[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble talking									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	8.33 (15.08)	-3.39 (5.29)	17	15.69 (23.91)	7.76 (3.93)	-11.15 (-23.89, 1.59)	-0.76 (-1.64, 0.12)	0.0818

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-sa.rtf

Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	13	7 (53.8)	2.9 (0.1, NE)	17	5 (29.4)	NR (6.4, NE)	3.765 (0.748, 18.944)	0.0754
Eating	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	NR (0.8, NE)	0.269 (0.030, 2.390)	0.2122
Reflux	13	2 (15.4)	NR (1.9, NE)	17	6 (35.3)	NR (1.4, NE)	0.499 (0.090, 2.772)	0.4197
Pain	13	1 (7.7)	NR (NE, NE)	17	5 (29.4)	24.4 (0.8, NE)	0.648 (0.055, 7.567)	0.7273
Trouble Swallowing Saliva	13	1 (7.7)	NR (NE, NE)	17	6 (35.3)	NR (1.0, NE)	0.242 (0.026, 2.297)	0.1857
Choked When Swallowing	13	1 (7.7)	NR (2.3, NE)	17	5 (29.4)	NR (1.5, NE)	0.324 (0.035, 3.050)	0.3032

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dry Mouth	13	3 (23.1)	NR (2.3, NE)	17	9 (52.9)	2.2 (0.7, NE)	0.393 (0.095, 1.630)	0.1859
Trouble With Taste	13	2 (15.4)	NR (2.8, NE)	17	8 (47.1)	3.3 (0.8, NE)	0.279 (0.056, 1.384)	0.0975
Trouble With Coughing	13	3 (23.1)	26.0 (0.7, NE)	17	4 (23.5)	NR (2.2, NE)	0.648 (0.103, 4.061)	0.6402
Trouble Talking	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (3.2, NE)	0.000 (0.000, NE)	0.2489

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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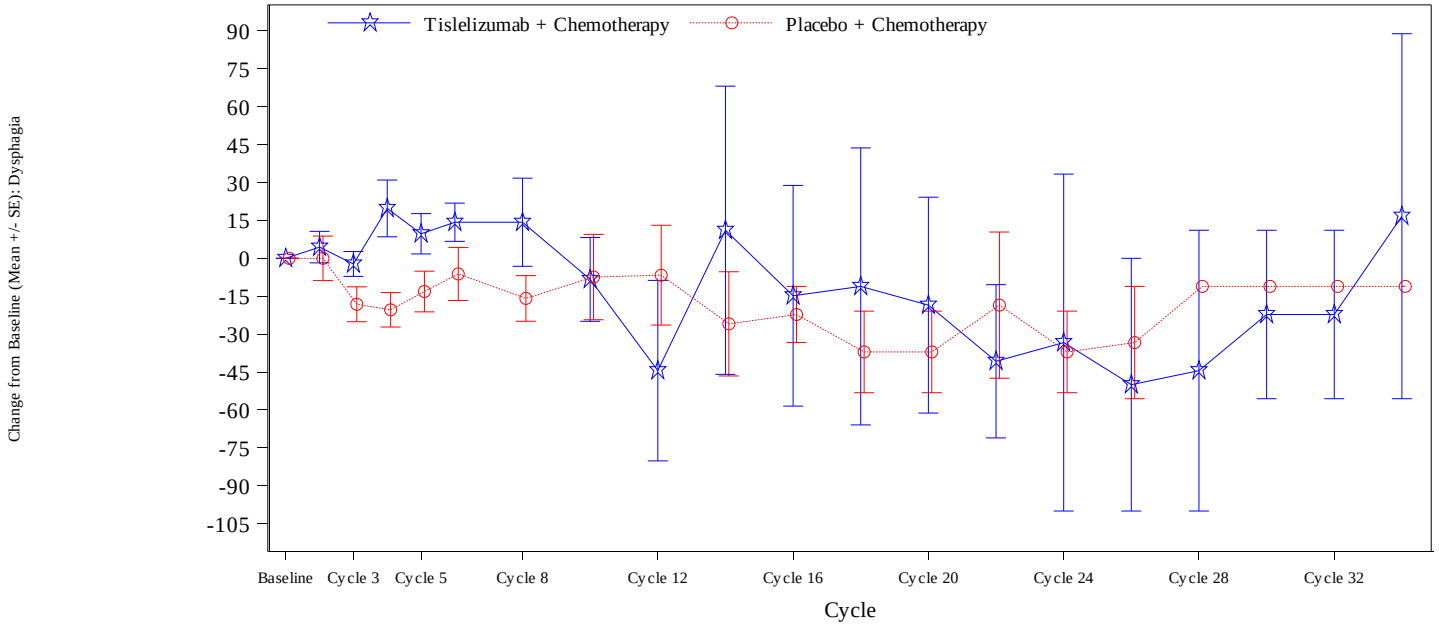
Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
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Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

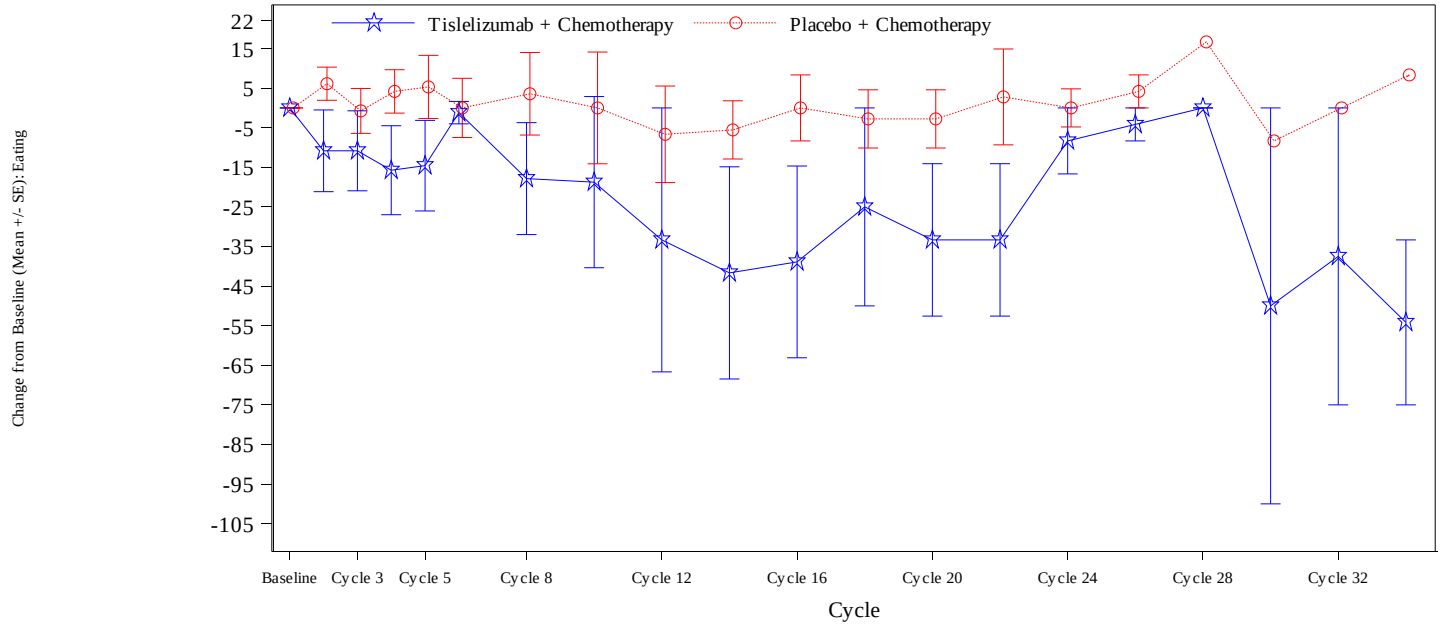

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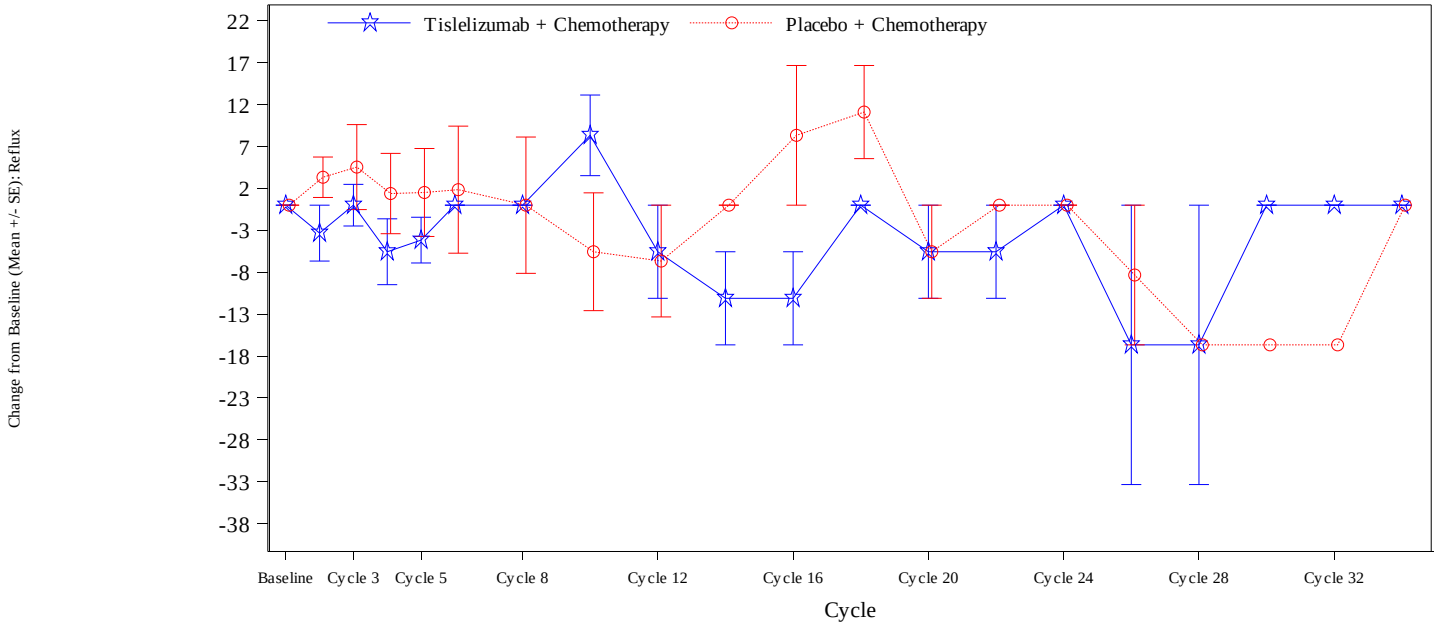
Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	2	2
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Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
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Figure 14.2.7.2:
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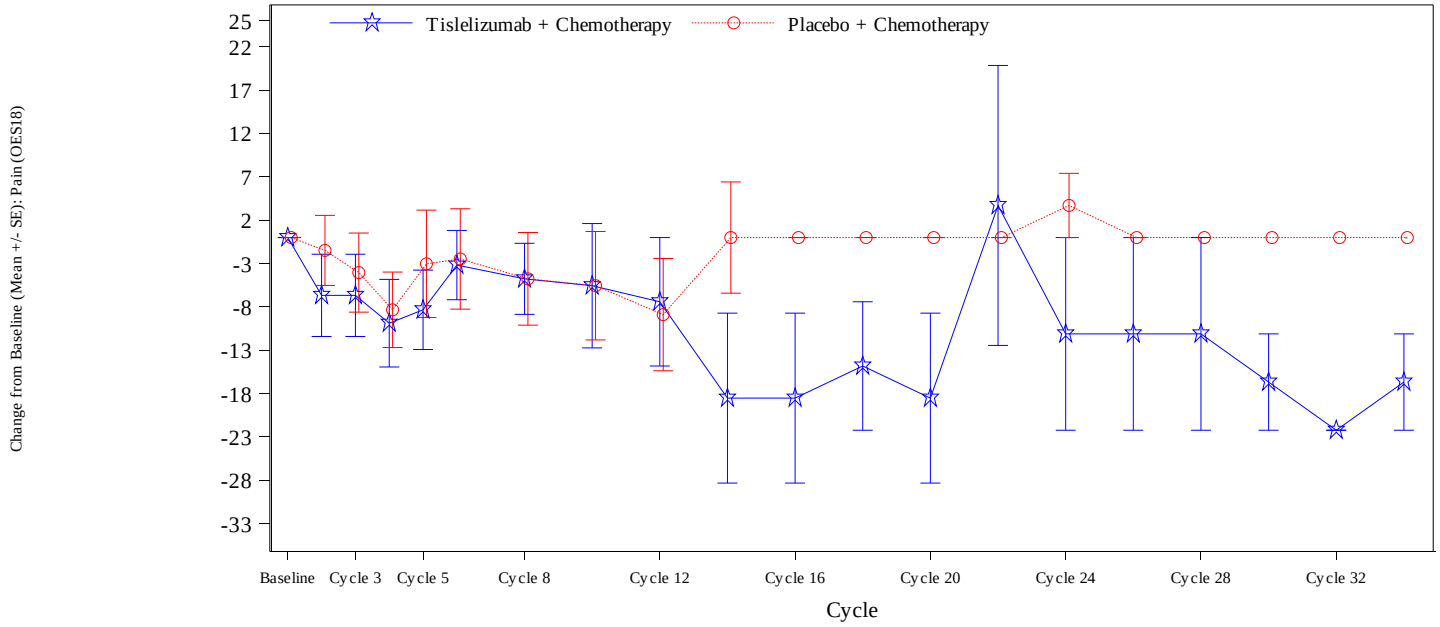
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
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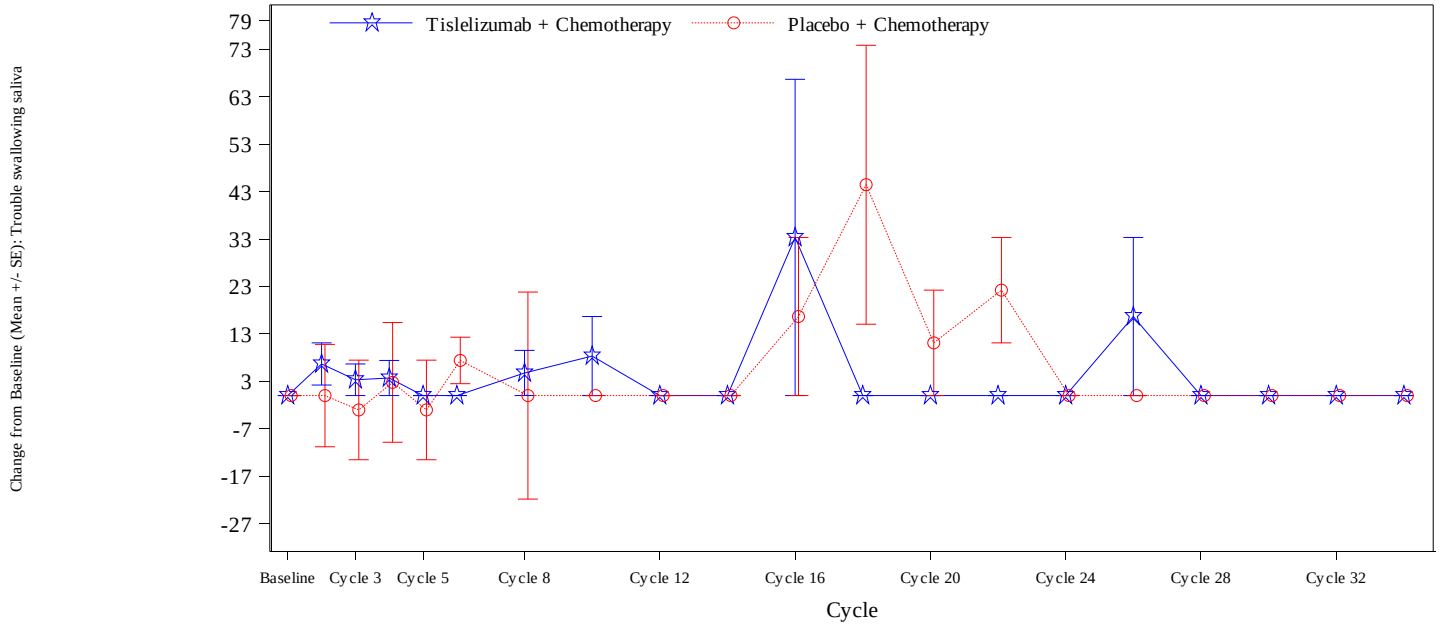
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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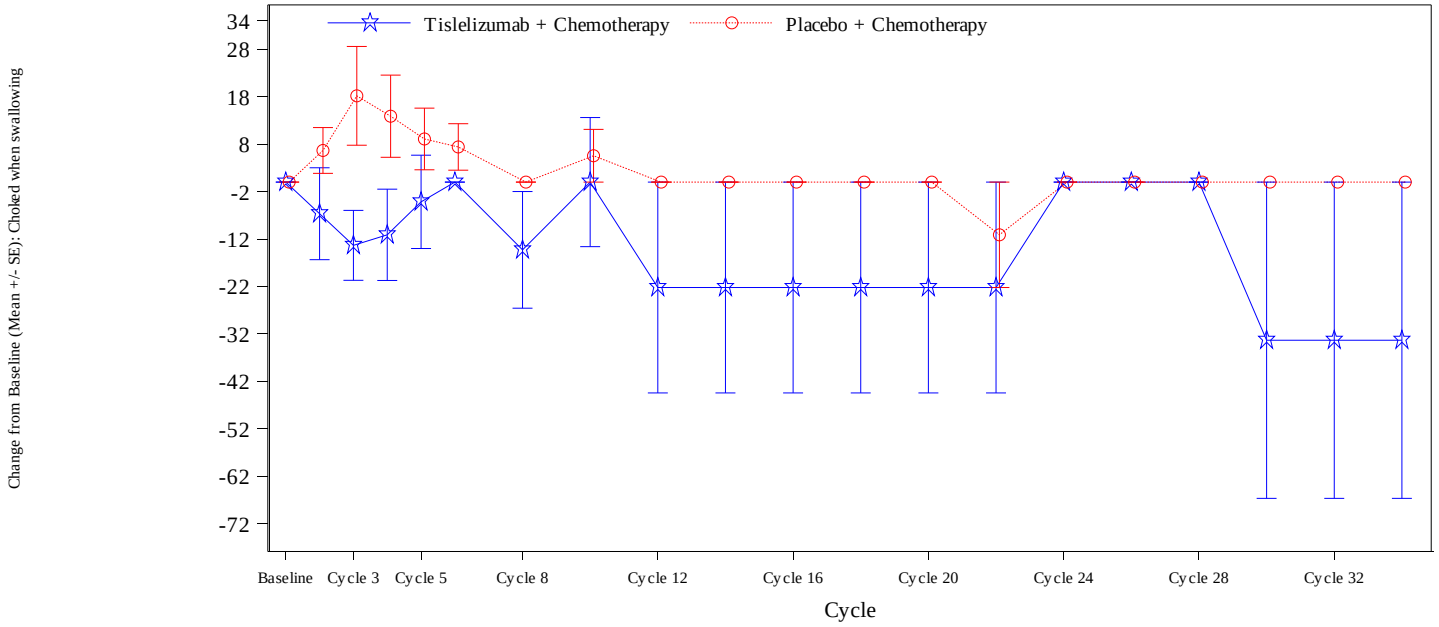

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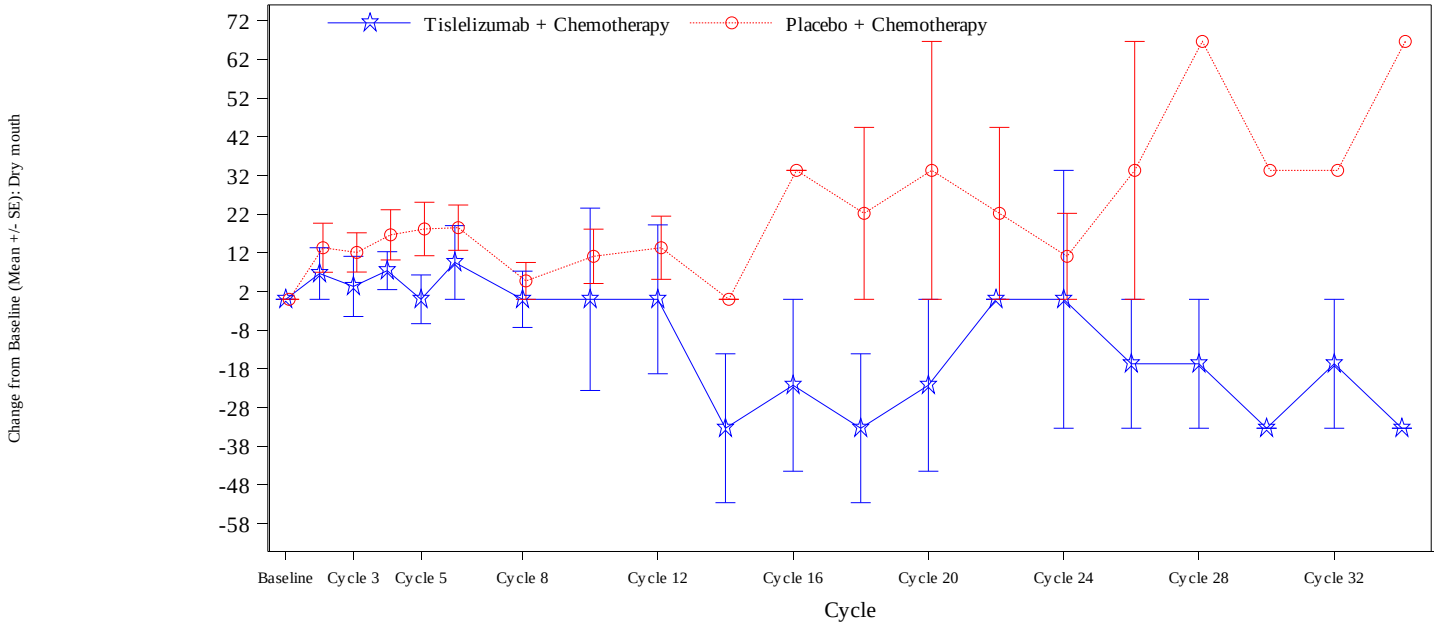
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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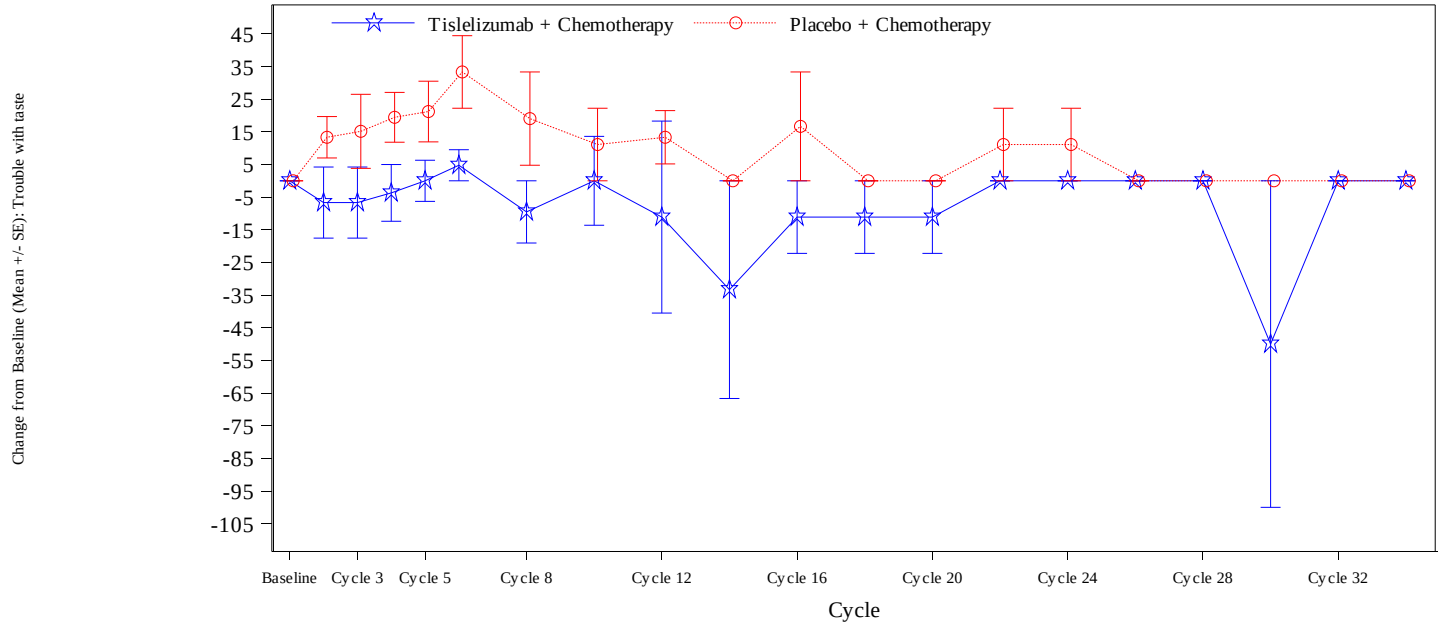

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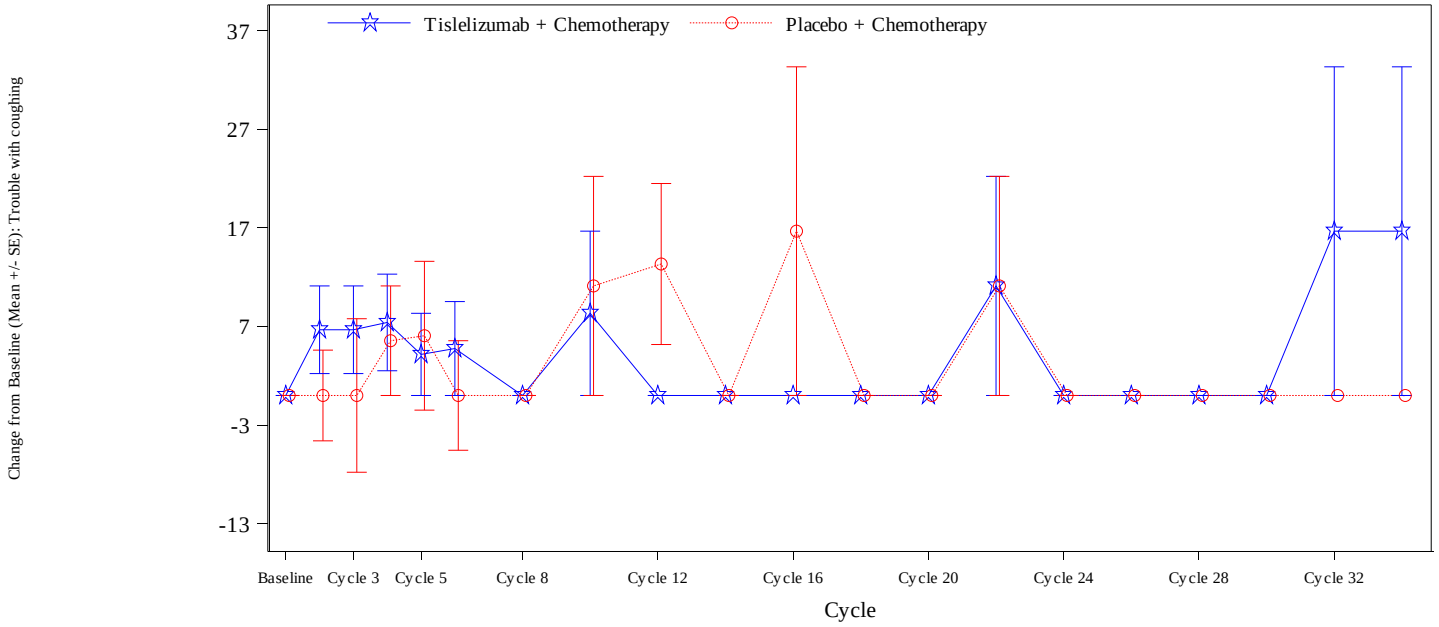
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

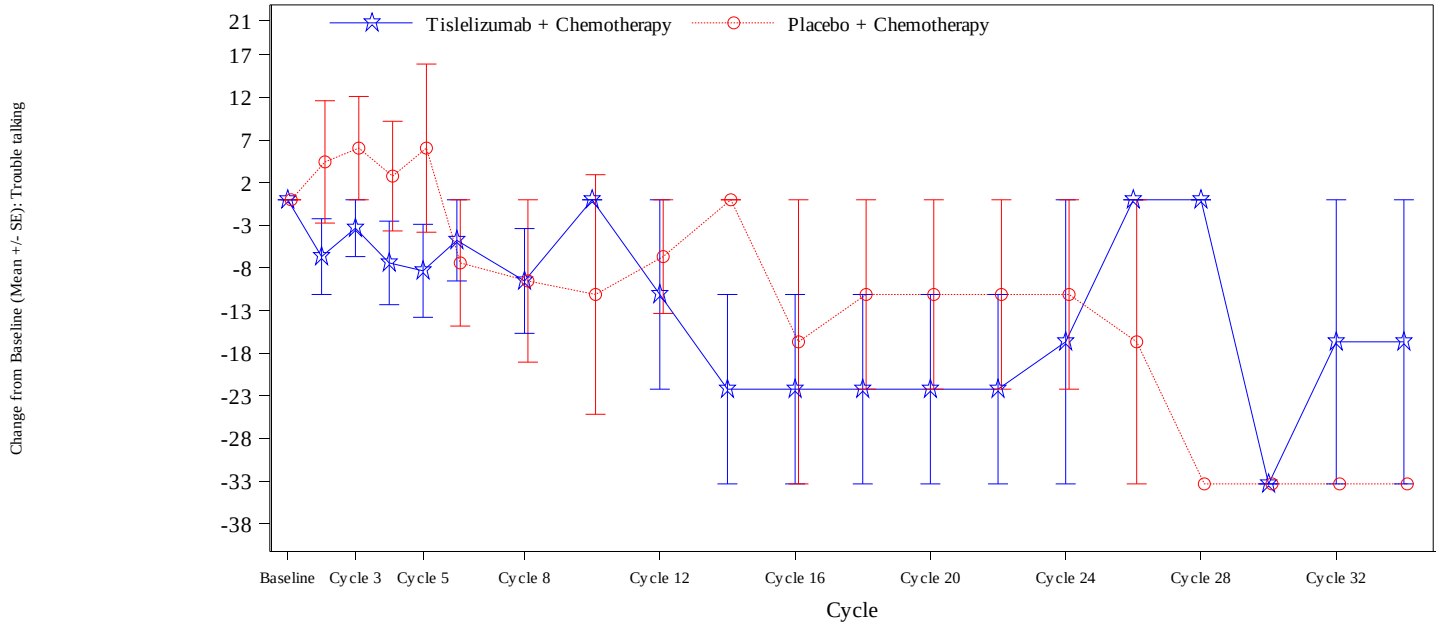

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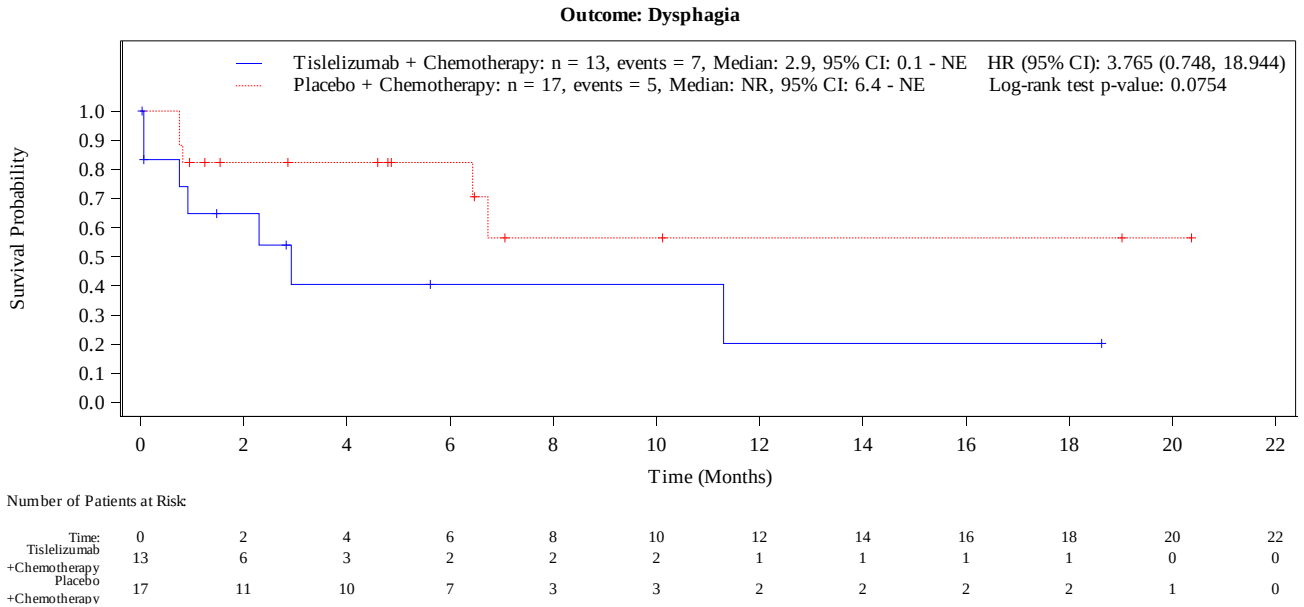
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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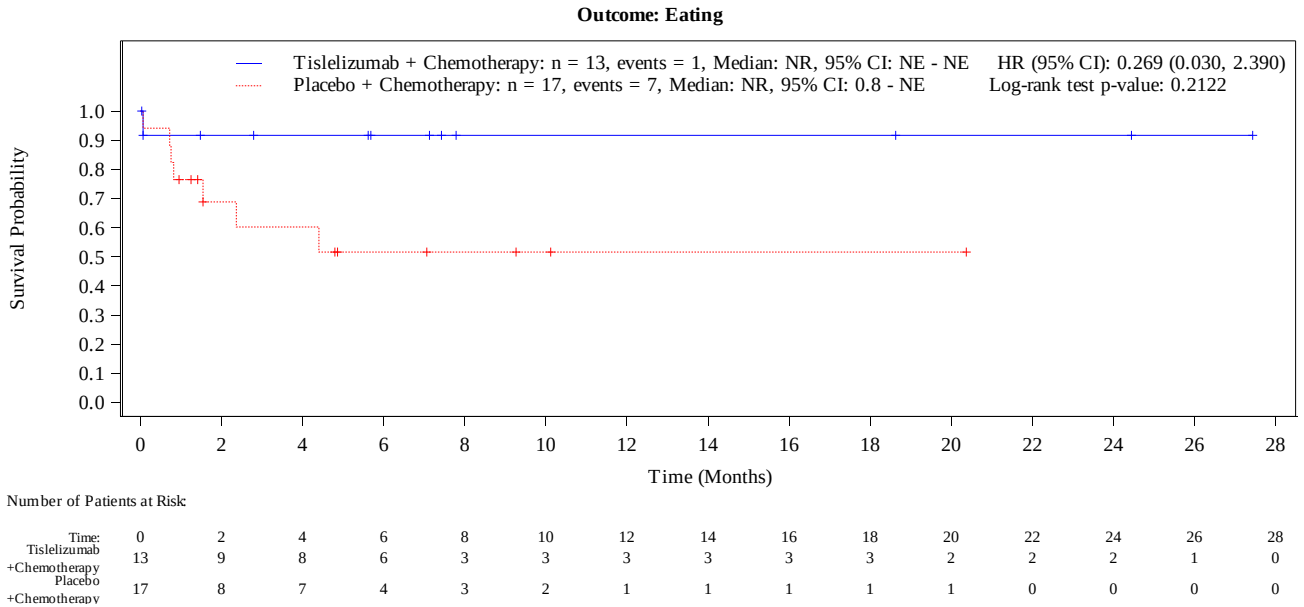
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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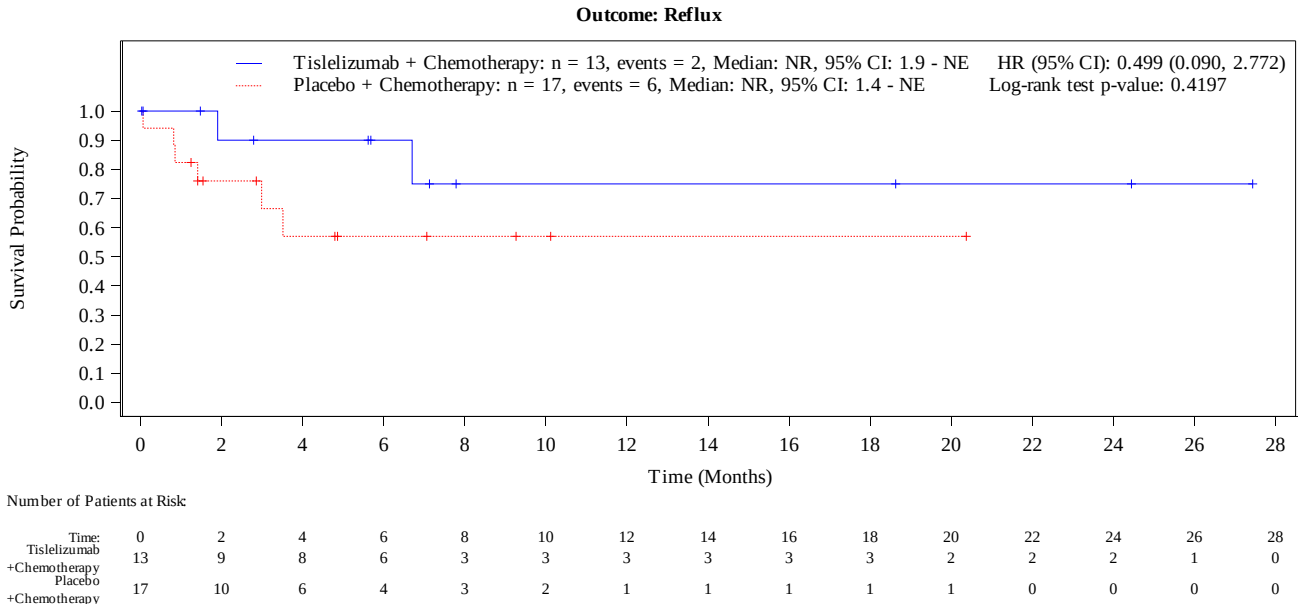

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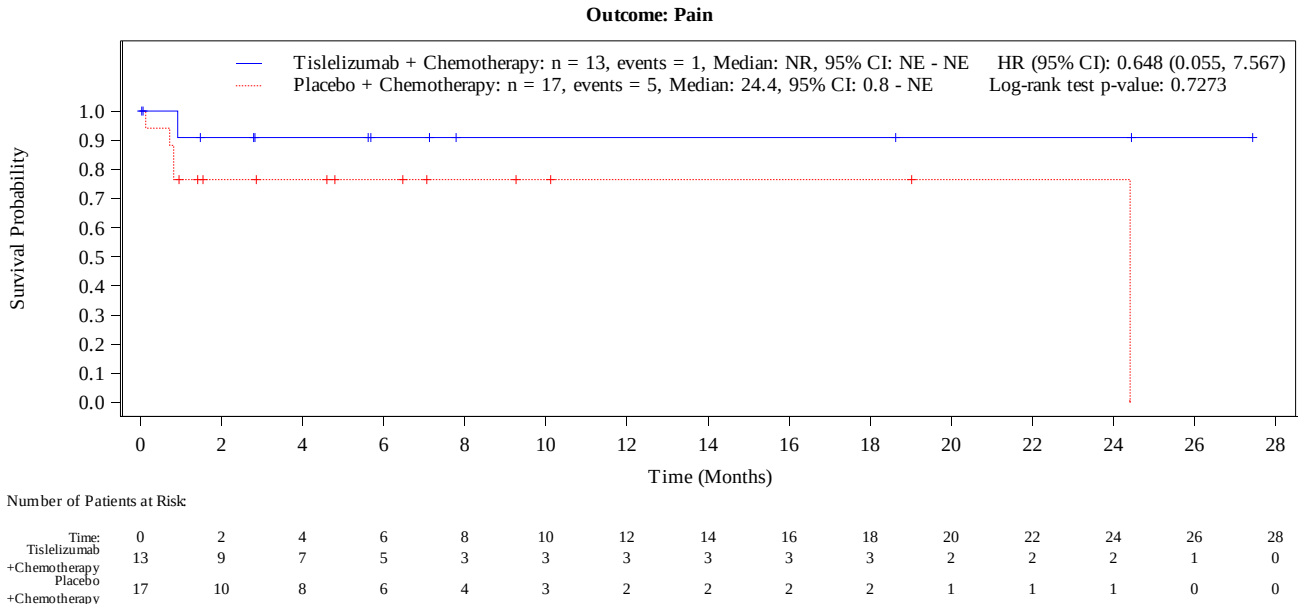

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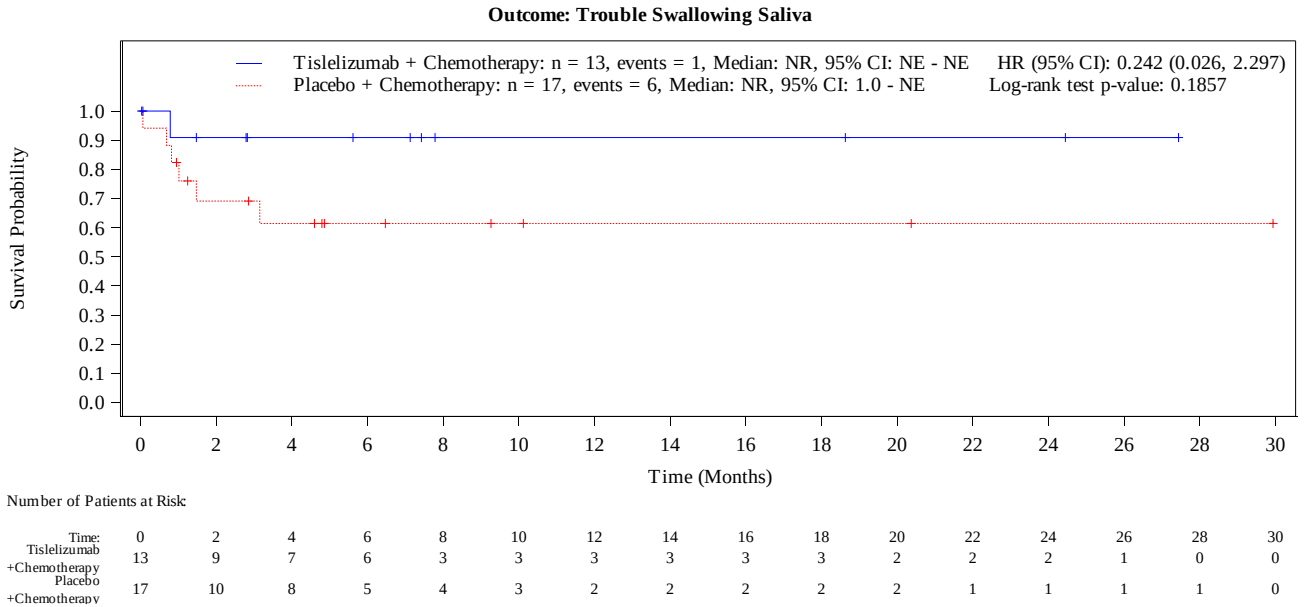
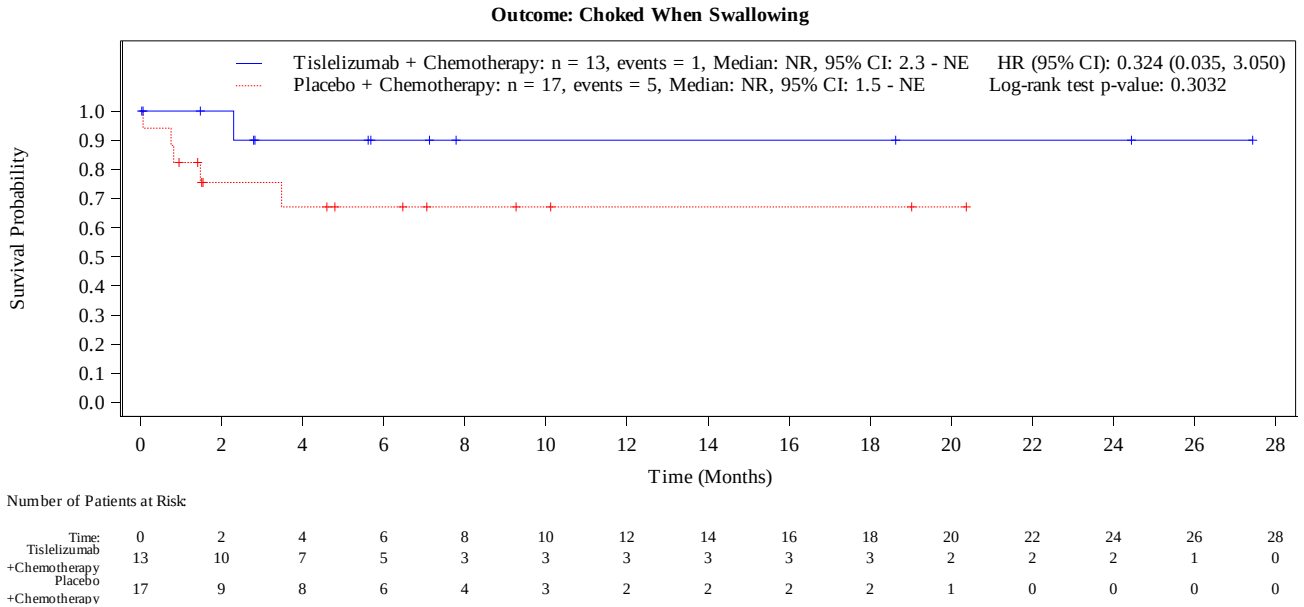
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-sa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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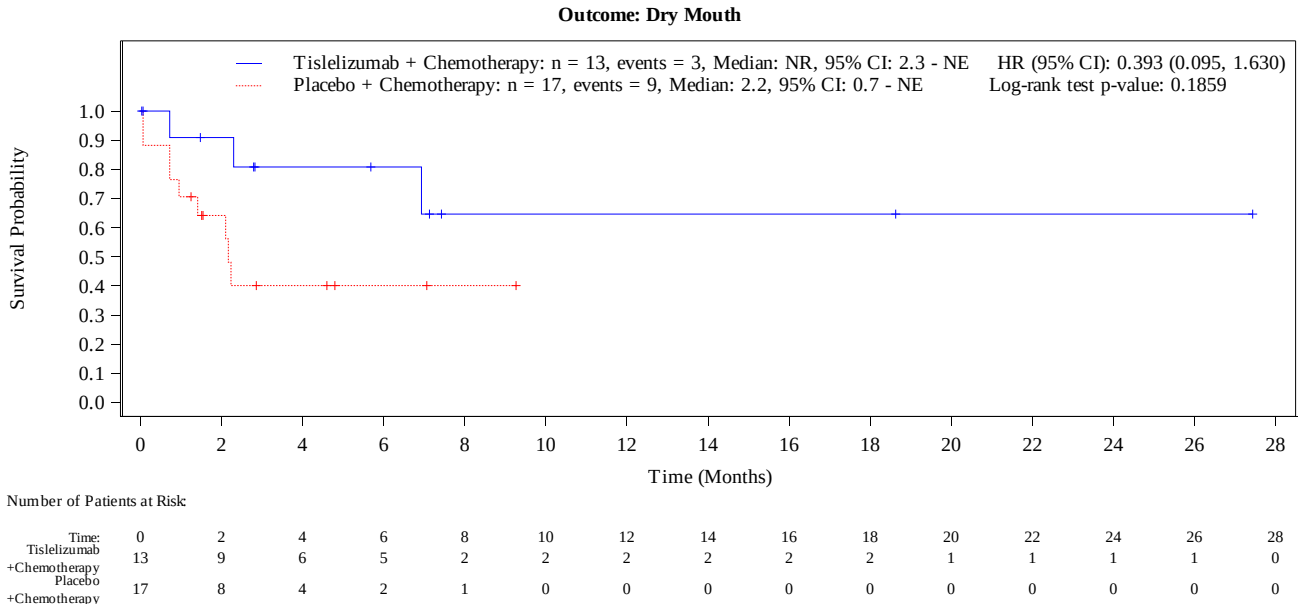
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-sa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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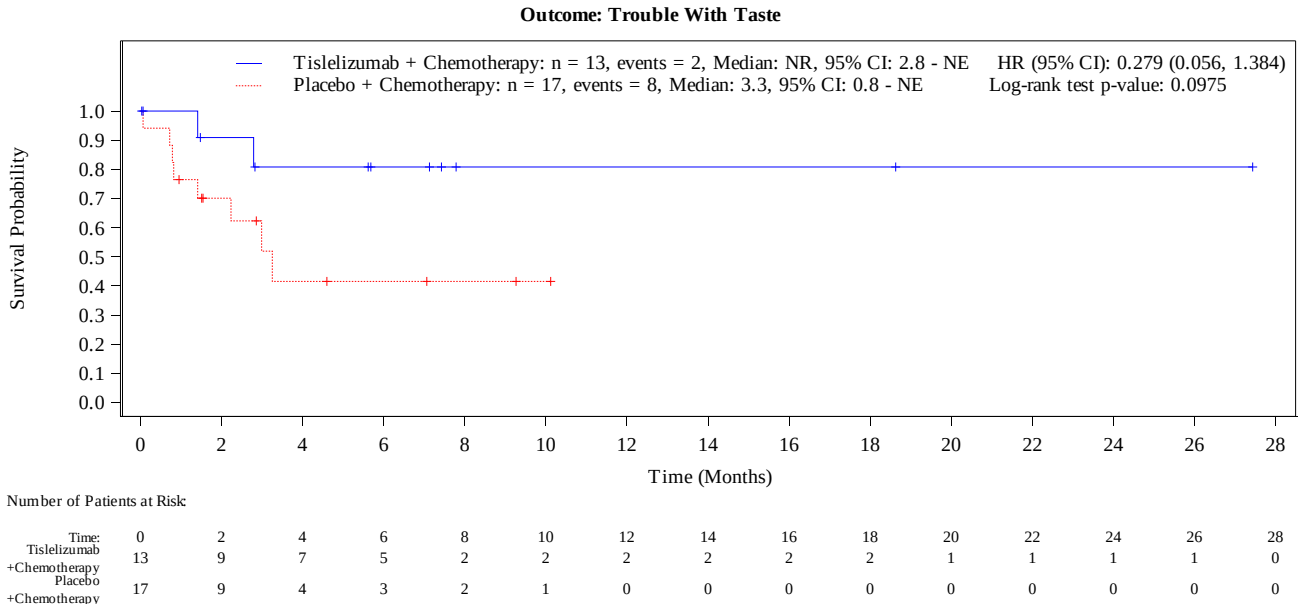
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
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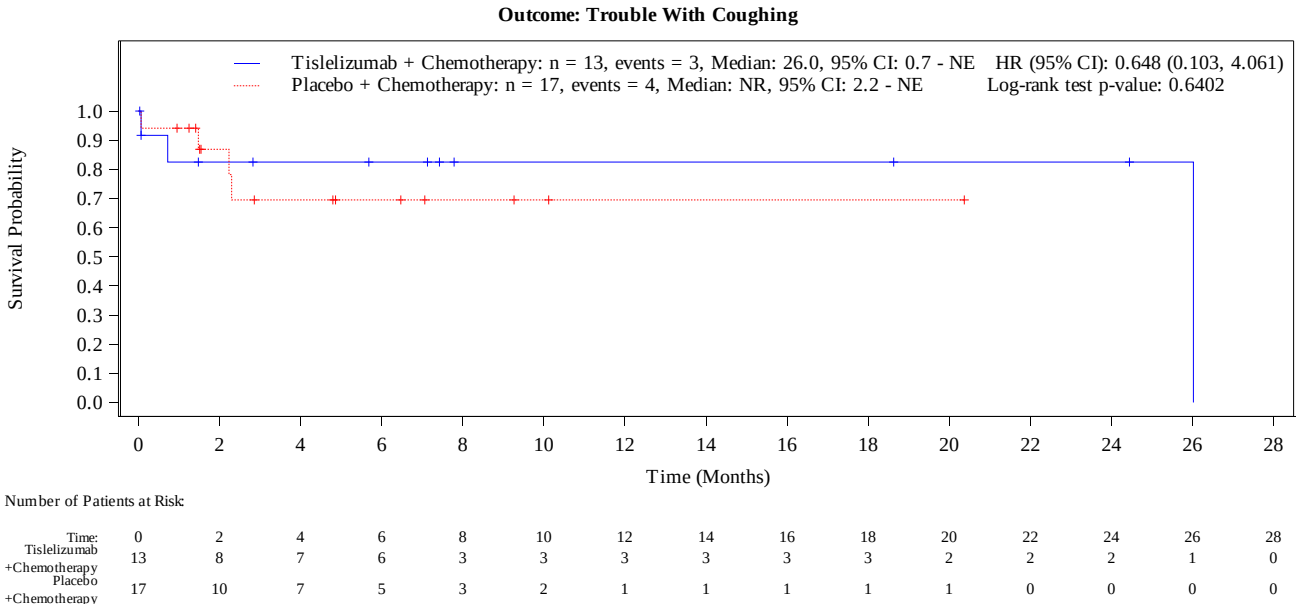
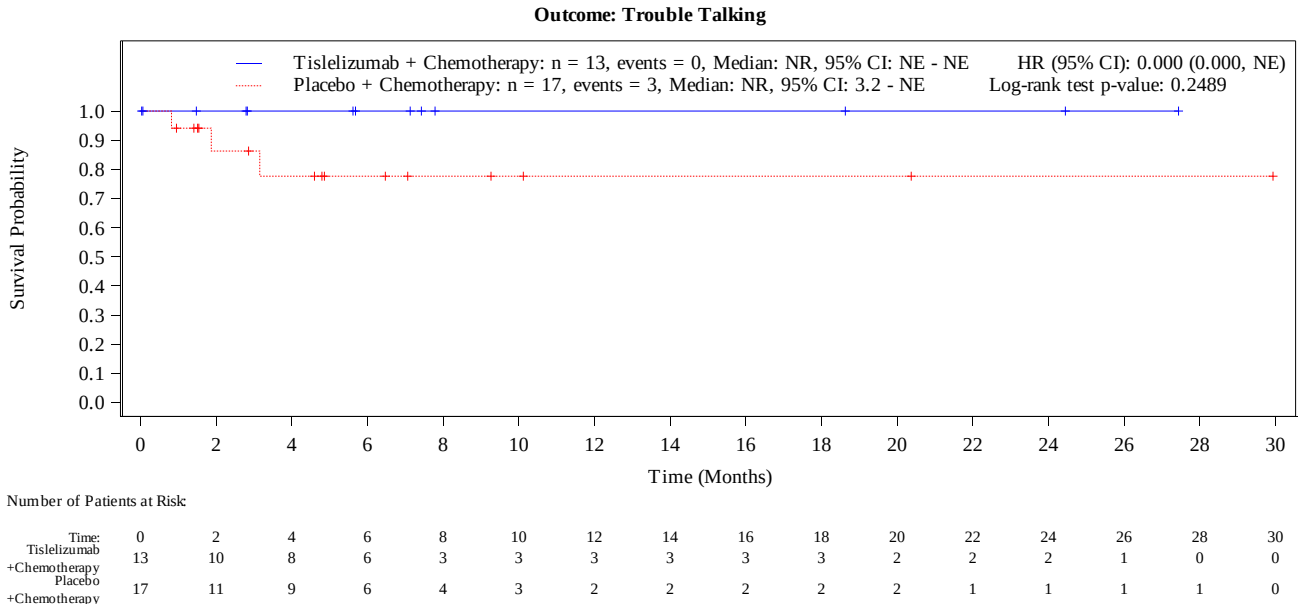
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-sa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
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Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	5 (55.6)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	4 (36.4)	--	--	--
Female	4	3 (75.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	2 (20.0)	--	--	--
1	6	3 (50.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	3 (42.9)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	1 (11.1)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	4 (57.1)	--	--	--
No	9	1 (11.1)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	1 (11.1)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

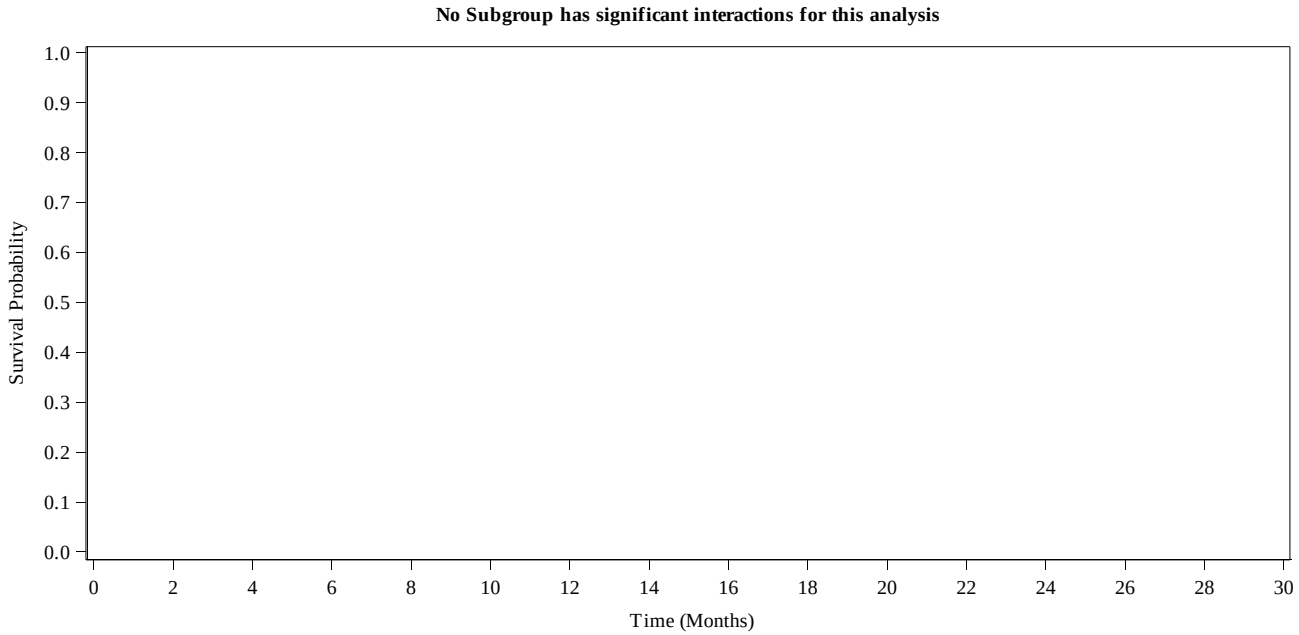
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-sa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-2-2-s-km-tteqs-subgrp-oes-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	70.6 (26.11)		64.8 (19.76)	
	Median	77.0		69.0	
	Q1, Q3	51.0, 90.0		51.0, 80.0	
	Min, Max	13, 98		20, 92	
Cycle 2	n	10	10	15	15
	Mean (SD)	77.7 (17.80)	7.4 (29.15)	67.8 (19.24)	3.7 (15.57)
	Median	80.0	2.0	75.0	5.0
	Q1, Q3	76.0, 89.0	-10.0, 13.0	61.0, 80.0	-9.0, 15.0
	Min, Max	40, 98	-39, 63	20, 88	-23, 28
Cycle 3	n	10	10	12	12
	Mean (SD)	79.2 (12.62)	8.9 (20.30)	69.1 (23.00)	2.5 (20.25)
	Median	81.0	6.0	75.5	2.0
	Q1, Q3	69.0, 90.0	-8.0, 15.0	65.0, 84.0	-9.5, 19.5
	Min, Max	59, 95	-10, 47	20, 95	-33, 27

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	78.4 (18.41)	9.1 (16.47)	65.8 (22.06)	-0.8 (20.74)
	Median	80.0	8.0	75.0	-0.5
	Q1, Q3	79.0, 92.0	-3.0, 17.0	55.0, 80.0	-17.5, 16.0
	Min, Max	39, 96	-11, 39	21, 91	-31, 35
Cycle 5	n	8	8	11	11
	Mean (SD)	80.9 (14.97)	9.4 (17.34)	72.0 (16.73)	3.9 (20.78)
	Median	85.0	9.0	75.0	4.0
	Q1, Q3	74.5, 90.0	-6.5, 22.0	70.0, 80.0	-10.0, 23.0
	Min, Max	50, 98	-11, 37	31, 100	-30, 35
Cycle 6	n	8	8	9	9
	Mean (SD)	79.9 (16.00)	8.4 (16.29)	73.0 (19.69)	1.9 (22.62)
	Median	84.0	8.5	76.0	0.0
	Q1, Q3	72.5, 90.5	-7.5, 20.0	70.0, 80.0	-12.0, 24.0
	Min, Max	48, 97	-10, 35	27, 100	-34, 31

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	80.6 (19.26)	9.6 (15.74)	81.3 (9.23)	6.0 (16.64)
	Median	87.0	5.0	80.0	0.0
	Q1, Q3	75.0, 95.0	-3.0, 27.0	79.0, 81.0	-9.0, 20.0
	Min, Max	40, 95	-8, 34	69, 100	-12, 35
Cycle 10	n	4	4	6	6
	Mean (SD)	79.0 (27.22)	18.5 (18.16)	78.7 (15.33)	4.2 (22.66)
	Median	88.0	16.0	80.0	4.0
	Q1, Q3	60.5, 97.5	3.5, 33.5	79.0, 81.0	-10.0, 21.0
	Min, Max	40, 100	2, 40	52, 100	-29, 35
Cycle 12	n	3	3	5	5
	Mean (SD)	63.7 (25.11)	13.0 (18.52)	79.0 (13.06)	8.0 (24.58)
	Median	61.0	20.0	79.0	7.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	75.0, 86.0	-11.0, 30.0
	Min, Max	40, 90	-8, 27	60, 95	-21, 35

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	77.7 (22.23)	27.0 (30.81)	76.3 (6.35)	3.0 (16.09)
	Median	90.0	39.0	80.0	1.0
	Q1, Q3	52.0, 91.0	-8.0, 50.0	69.0, 80.0	-12.0, 20.0
	Min, Max	52, 91	-8, 50	69, 80	-12, 20
Cycle 16	n	3	3	2	2
	Mean (SD)	71.0 (19.00)	20.3 (24.95)	74.0 (7.07)	-11.5 (0.71)
	Median	71.0	30.0	74.0	-11.5
	Q1, Q3	52.0, 90.0	-8.0, 39.0	69.0, 79.0	-12.0, -11.0
	Min, Max	52, 90	-8, 39	69, 79	-12, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	63.3 (25.17)	12.7 (18.34)	76.7 (5.77)	-6.7 (6.66)
	Median	60.0	19.0	80.0	-10.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	70.0, 80.0	-11.0, 1.0
	Min, Max	40, 90	-8, 27	70, 80	-11, 1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	75.0 (21.79)	24.3 (28.22)	80.3 (0.58)	-3.0 (6.08)
	Median	85.0	37.0	80.0	0.0
	Q1, Q3	50.0, 90.0	-8.0, 44.0	80.0, 81.0	-10.0, 1.0
	Min, Max	50, 90	-8, 44	80, 81	-10, 1
Cycle 22	n	3	3	3	3
	Mean (SD)	70.3 (30.01)	19.7 (15.37)	76.3 (7.23)	-7.0 (13.08)
	Median	71.0	27.0	80.0	-1.0
	Q1, Q3	40.0, 100.0	2.0, 30.0	68.0, 81.0	-22.0, 2.0
	Min, Max	40, 100	2, 30	68, 81	-22, 2
Cycle 24	n	2	2	3	3
	Mean (SD)	86.0 (7.07)	16.5 (33.23)	78.0 (7.21)	-5.3 (13.05)
	Median	86.0	16.5	80.0	-1.0
	Q1, Q3	81.0, 91.0	-7.0, 40.0	70.0, 84.0	-20.0, 5.0
	Min, Max	81, 91	-7, 40	70, 84	-20, 5

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	3	3	2	2
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	83.0 (4.24)	-1.5 (3.54)
	Median	71.0	30.0	83.0	-1.5
	Q1, Q3	50.0, 90.0	-8.0, 37.0	80.0, 86.0	-4.0, 1.0
	Min, Max	50, 90	-8, 37	80, 86	-4, 1
Cycle 28	n	3	3	1	1
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	71.0 (NE)	-19.0 (NE)
	Median	71.0	30.0	71.0	-19.0
	Q1, Q3	50.0, 90.0	-8.0, 37.0	71.0, 71.0	-19.0, -19.0
	Min, Max	50, 90	-8, 37	71, 71	-19, -19
Cycle 30	n	2	2	1	1
	Mean (SD)	65.5 (21.92)	38.5 (2.12)	79.0 (NE)	-11.0 (NE)
	Median	65.5	38.5	79.0	-11.0
	Q1, Q3	50.0, 81.0	37.0, 40.0	79.0, 79.0	-11.0, -11.0
	Min, Max	50, 81	37, 40	79, 79	-11, -11

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	2	2	1	1
	Mean (SD)	66.5 (21.92)	39.5 (2.12)	81.0 (NE)	-9.0 (NE)
	Median	66.5	39.5	81.0	-9.0
	Q1, Q3	51.0, 82.0	38.0, 41.0	81.0, 81.0	-9.0, -9.0
	Min, Max	51, 82	38, 41	81, 81	-9, -9
Cycle 34	n	2	2	1	1
	Mean (SD)	64.5 (21.92)	37.5 (2.12)	87.0 (NE)	-3.0 (NE)
	Median	64.5	37.5	87.0	-3.0
	Q1, Q3	49.0, 80.0	36.0, 39.0	87.0, 87.0	-3.0, -3.0
	Min, Max	49, 80	36, 39	87, 87	-3, -3
Cycle 36	n	1	1	1	1
	Mean (SD)	49.0 (NE)	36.0 (NE)	70.0 (NE)	-20.0 (NE)
	Median	49.0	36.0	70.0	-20.0
	Q1, Q3	49.0, 49.0	36.0, 36.0	70.0, 70.0	-20.0, -20.0
	Min, Max	49, 49	36, 36	70, 70	-20, -20

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			95.0 (NE)	5.0 (NE)
	Median			95.0	5.0
	Q1, Q3			95.0, 95.0	5.0, 5.0
	Min, Max			95, 95	5, 5
Cycle 40	n	0	0	1	1
	Mean (SD)			70.0 (NE)	-20.0 (NE)
	Median			70.0	-20.0
	Q1, Q3			70.0, 70.0	-20.0, -20.0
	Min, Max			70, 70	-20, -20
Cycle 42	n	0	0	1	1
	Mean (SD)			70.0 (NE)	-20.0 (NE)
	Median			70.0	-20.0
	Q1, Q3			70.0, 70.0	-20.0, -20.0
	Min, Max			70, 70	-20, -20

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			65.0 (NE)	-25.0 (NE)
	Median			65.0	-25.0
	Q1, Q3			65.0, 65.0	-25.0, -25.0
	Min, Max			65, 65	-25, -25
End of Treatment	n	9	9	14	14
	Mean (SD)	68.8 (25.21)	-7.4 (32.80)	62.2 (26.18)	-1.4 (18.36)
	Median	77.0	-8.0	70.0	0.5
	Q1, Q3	60.0, 82.0	-13.0, 8.0	48.0, 78.0	-9.0, 10.0
	Min, Max	10, 94	-80, 41	10, 100	-40, 25

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	59.4 (25.75)	-11.2 (26.27)	55.3 (20.11)	-9.5 (17.46)
	Median	60.5	-8.0	60.0	-3.0
	Q1, Q3	40.0, 80.0	-11.5, 1.0	49.0, 67.0	-25.0, 2.0
	Min, Max	10, 94	-80, 26	10, 85	-40, 15

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-sa.rtf

Table 14.2.6.5.1.1:
EQ-5D-VAS: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
EQ-5D VAS									
Cycle 6	8		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	70.58 (26.11)	5.88 (4.76)	17	64.76 (19.76)	3.75 (3.66)	2.13 (-8.79, 13.05)	0.17 (-0.68, 1.01)	0.6902

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+ chemotherapy arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.5.1.2:
Analyses of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	13	1 (7.7)	NR (NE, NE)	17	4 (23.5)	14.7 (3.2, NE)	0.636 (0.066, 6.122)	0.6928

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

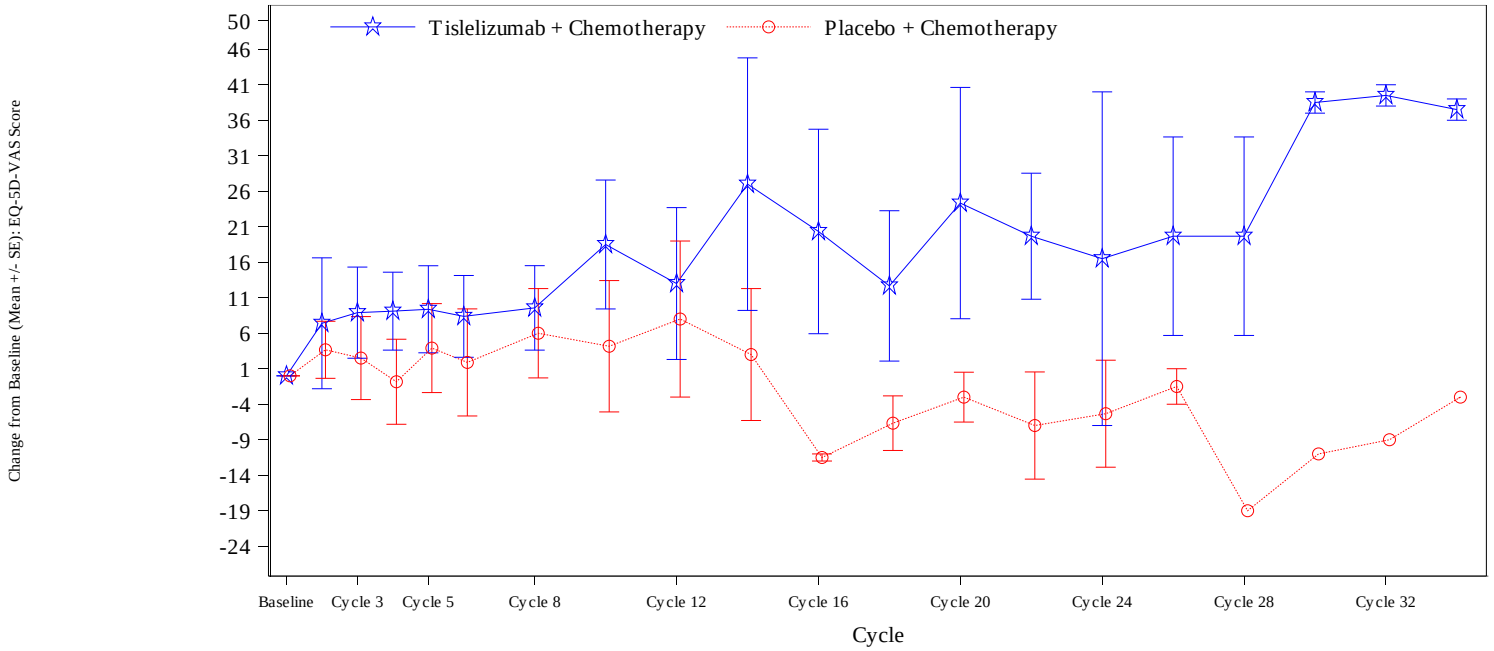
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-5-1-2-eff-tte-qlq-vas-pop1-sa.rtf

Figure 14.2.7.4:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

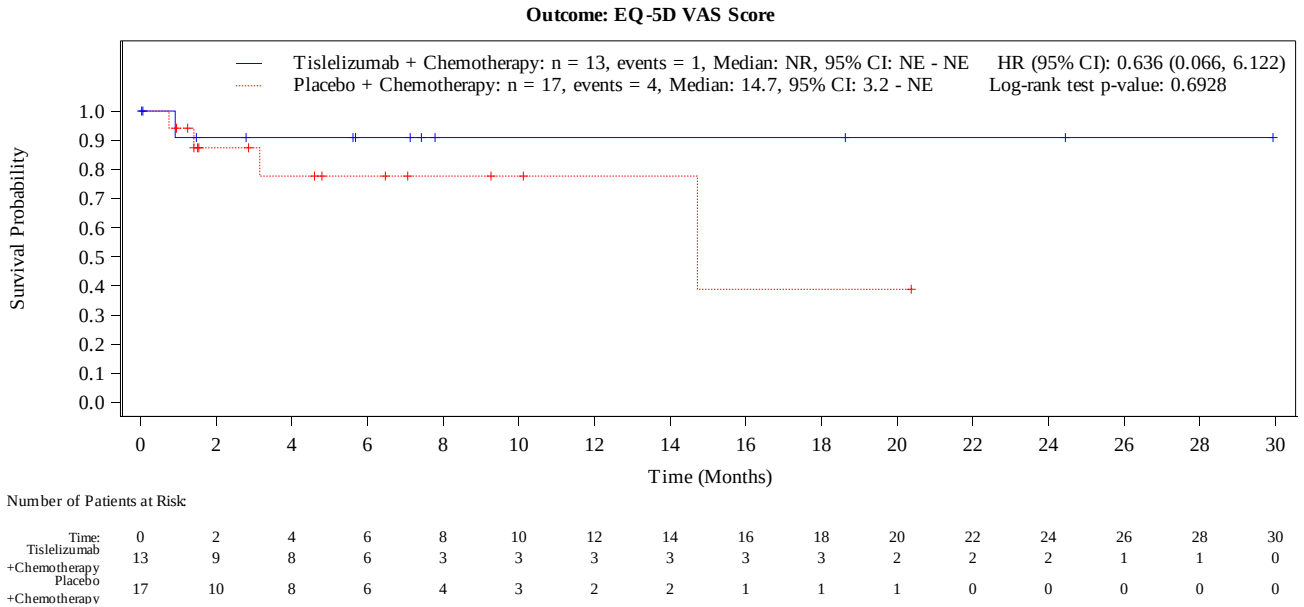


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	8	7	4	3	3	3	3	3	3	2	3	3	2	2	2
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	2	1	1	1	1

Source: ADQS. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-4-series-eq5d-pop1-sa.rtf

Figure 14.2.7.4.2:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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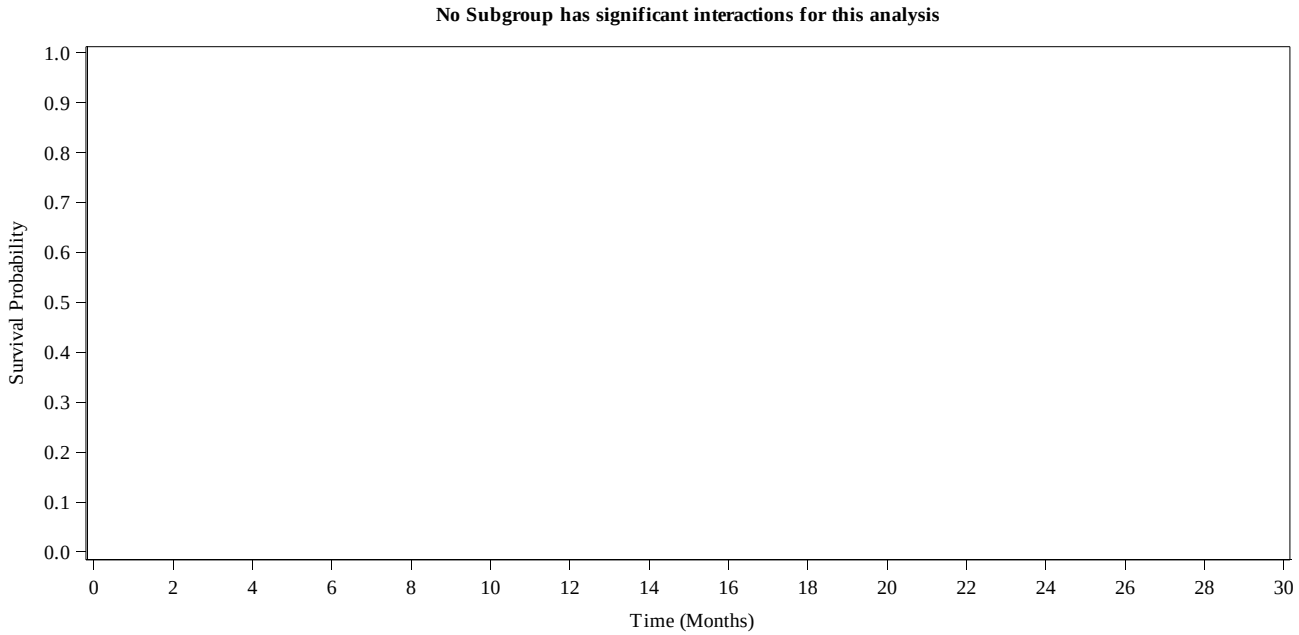
Figure 14.2.7.4.2.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Patients with Any Subsequent Anti-Cancer Therapy, n (%)	9 (69.2)	13 (76.5)
Radiotherapy	2 (15.4)	6 (35.3)
Procedure or Surgery	1 (7.7)	2 (11.8)
Systemic Therapy	9 (69.2)	12 (70.6)
Immunotherapy	4 (30.8)	7 (41.2)
Time to First Post-Treatment Anti-Cancer Therapy (months)		
n	9	13
Mean (SD)	2.08 (1.986)	2.05 (2.757)
Median	0.99	1.61
Q1, Q3	0.79, 3.32	0.56, 2.07
Min, Max	0.6, 6.0	0.3, 10.8

Source: ADCM, ADPR, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.
Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-sa.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Time to First Post-Treatment Immunotherapy (months)		
n	4	7
Mean (SD)	4.94 (5.508)	2.70 (2.322)
Median	3.45	2.63
Q1, Q3	0.69, 9.18	0.56, 4.27
Min, Max	0.6, 12.3	0.3, 6.8
Post-Treatment Anti-Cancer Therapy Duration (months)		
Systemic Therapy		
n	9	12
Mean (SD)	10.58 (7.360)	5.31 (6.420)
Median	10.22	2.99
Q1, Q3	4.40, 14.49	0.92, 7.56
Min, Max	1.2, 25.1	0.0, 21.6
Patients with Ongoing Anti-Cancer Systemic Therapy at Data Cutoff, n (%)	1 (7.7)	1 (5.9)

Source: ADCM, ADPR, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Percentages were based on N.

Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.

Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Immunotherapy		
n	4	7
Mean (SD)	2.15 (1.988)	3.10 (3.619)
Median	1.41	1.64
Q1, Q3	0.89, 3.42	0.03, 7.62
Min, Max	0.7, 5.1	0.0, 8.9
Patients with Ongoing Immunotherapy at Data Cutoff, n (%)	0 (0.0)	0 (0.0)

Source: ADCM, ADPR, ADBASE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.
Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-sa.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Duration of Treatment (month) [a]			
n	13	17	30
Mean (SD)	12.57 (14.044)	7.58 (8.796)	9.74 (11.429)
Median	5.65	4.14	5.22
Q1, Q3	2.76, 24.11	1.58, 8.77	2.53, 10.25
Min, Max	0.7, 44.0	0.7, 32.6	0.7, 44.0
Duration of Treatment, n (%)			
< 1 month	2 (15.4)	2 (11.8)	4 (13.3)
≥ 1 to < 3 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 3 to < 6 months	3 (23.1)	4 (23.5)	7 (23.3)
≥ 6 to < 12 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 12 to < 18 months	0 (0.0)	0 (0.0)	0 (0.0)
≥ 18 to < 24 months	0 (0.0)	2 (11.8)	2 (6.7)
≥ 24 months	4 (30.8)	1 (5.9)	5 (16.7)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Number of Cycles Received			
n	13	17	30
Mean (SD)	16.6 (18.05)	9.4 (10.85)	12.5 (14.60)
Median	8.0	5.0	7.5
Q1, Q3	4.0, 34.0	2.0, 12.0	3.0, 14.0
Min, Max	1, 54	1, 42	1, 54
Number of Cycles Received, n (%)			
1-3	3 (23.1)	7 (41.2)	10 (33.3)
4-6	1 (7.7)	3 (17.6)	4 (13.3)
7-9	4 (30.8)	1 (5.9)	5 (16.7)
10-12	1 (7.7)	2 (11.8)	3 (10.0)
13-18	0 (0.0)	2 (11.8)	2 (6.7)
19-24	0 (0.0)	0 (0.0)	0 (0.0)
25-36	2 (15.4)	1 (5.9)	3 (10.0)
>36	2 (15.4)	1 (5.9)	3 (10.0)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Cumulative Total Dose (mg) per Patient [b]			
n	13	17	30
Mean (SD)	3323.08 (3610.668)	1870.59 (2170.186)	2500.00 (2920.439)
Median	1600.00	1000.00	1500.00
Q1, Q3	800.00, 6800.00	400.00, 2400.00	600.00, 2800.00
Min, Max	200.0, 10800.0	200.0, 8400.0	200.0, 10800.0
Actual Dose Intensity (mg/cycle) per Patient [c]			
n	13	17	30
Mean (SD)	187.43 (14.809)	178.05 (26.275)	182.12 (22.225)
Median	194.92	186.67	188.61
Q1, Q3	174.19, 198.82	171.43, 198.11	171.43, 198.82
Min, Max	161.5, 200.0	112.4, 200.0	112.4, 200.0

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Relative Dose Intensity (%) per Patient [d]			
n	13	17	30
Mean (SD)	93.71 (7.404)	89.03 (13.137)	91.06 (11.113)
Median	97.46	93.33	94.31
Q1, Q3	87.10, 99.41	85.71, 99.06	85.71, 99.41
Min, Max	80.8, 100.0	56.2, 100.0	56.2, 100.0
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:37 t-14-3-1-1-1-ex-tis-pop1-sa.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Patients with Any Dose Modification, n (%)	8 (61.5)	11 (64.7)	19 (63.3)
Dose Delay	8 (61.5)	11 (64.7)	19 (63.3)
Adverse Event	3 (23.1)	10 (58.8)	13 (43.3)
Other	7 (53.8)	4 (23.5)	11 (36.7)
Related to COVID-19	2 (15.4)	2 (11.8)	4 (13.3)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	0 (0.0)	0 (0.0)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment (month) [a]				
n	13	13	17	17
Mean (SD)	4.12 (2.138)	7.27 (11.248)	3.51 (1.918)	5.08 (5.151)
Median	4.27	4.30	3.48	4.17
Q1, Q3	2.76, 4.90	2.79, 6.87	1.68, 4.40	1.71, 6.14
Min, Max	0.7, 8.3	0.7, 44.0	0.7, 7.2	0.7, 22.4

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment, n (%)				
< 1 month	2 (15.4)	2 (15.4)	2 (11.8)	2 (11.8)
≥ 1 to < 3 months	2 (15.4)	2 (15.4)	4 (23.5)	4 (23.5)
≥ 3 to < 6 months	7 (53.8)	5 (38.5)	9 (52.9)	6 (35.3)
≥ 6 to < 12 months	2 (15.4)	3 (23.1)	2 (11.8)	4 (23.5)
≥ 12 to ≤ 18 months	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
> 18 months	0 (0.0)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-chemo.sas 14NOV2024 00:36 t-14-3-1-1-2-ex-chemo-a-pop1-sa.rtf

Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received				
n	13	13	17	17
Mean (SD)	5.5 (2.67)	9.1 (12.89)	4.5 (2.45)	5.9 (4.55)
Median	6.0	6.0	5.0	5.0
Q1, Q3	4.0, 6.0	4.0, 8.0	2.0, 6.0	2.0, 8.0
Min, Max	1, 10	1, 51	1, 9	1, 17

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received, n (%)				
1-3	3 (23.1)	3 (23.1)	7 (41.2)	7 (41.2)
4-6	7 (53.8)	5 (38.5)	7 (41.2)	4 (23.5)
7-9	2 (15.4)	3 (23.1)	3 (17.6)	3 (17.6)
10-12	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)
13-18	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
>18	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Cumulative Total Dose (mg/m^2) per Patient [b]				
n	13	13	17	17
Mean (SD)	356.59 (173.633)	35771.80 (53377.563)	289.96 (155.327)	21636.25 (17662.020)
Median	359.07	22461.80	296.93	19909.72
Q1, Q3	276.36, 451.08	16162.38, 31793.25	164.68, 402.36	8162.99, 26944.39
Min, Max	71.9, 648.8	3671.0, 209891.7	59.9, 556.6	3749.5, 68382.0

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Actual Dose Intensity (mg/m^2/cycle) per Patient [c]				
n	13	13	17	17
Mean (SD)	62.39 (12.288)	3512.76 (363.810)	59.38 (12.483)	3169.15 (642.132)
Median	59.84	3504.12	58.30	3485.46
Q1, Q3	53.85, 73.42	3344.25, 3712.21	50.12, 67.03	2710.97, 3665.54
Min, Max	38.2, 80.6	2695.7, 3993.1	41.3, 82.3	2102.5, 3986.6

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Relative Dose Intensity (%) per Patient [d]				
n	13	13	17	17
Mean (SD)	87.64 (16.755)	90.53 (9.771)	82.39 (16.600)	79.75 (16.536)
Median	96.97	93.44	84.41	78.65
Q1, Q3	84.77, 99.22	83.86, 98.68	68.89, 97.17	67.77, 95.44
Min, Max	47.7, 100.7	67.4, 99.8	54.2, 102.9	52.6, 99.7
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	0 (0.0)	1 (5.9)	2 (11.8)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Patients with Any Dose Modification, n (%)	7 (53.8)	8 (61.5)	12 (70.6)	14 (82.4)
Dose Delay	7 (53.8)	7 (53.8)	9 (52.9)	10 (58.8)
Adverse Event	5 (38.5)	4 (30.8)	8 (47.1)	8 (47.1)
Other	3 (23.1)	5 (38.5)	1 (5.9)	3 (17.6)
Related to COVID-19	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	3 (23.1)	0 (0.0)	7 (41.2)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
Other	0 (0.0)	3 (23.1)	0 (0.0)	6 (35.3)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.
[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.
[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.
[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Dose Reduction	4 (30.8)	2 (15.4)	11 (64.7)	8 (47.1)
Adverse Event	4 (30.8)	2 (15.4)	9 (52.9)	8 (47.1)
Other	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	13	13 (100.0)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.1)	0.420 (0.145, 1.218)	0.1047
TEAE >= Grade 3	13	10 (76.9)	0.9 (0.2, 7.1)	17	14 (82.4)	1.0 (0.2, 2.1)	0.936 (0.313, 2.795)	0.9373
Serious TEAE	13	4 (30.8)	NR (5.0, NE)	17	6 (35.3)	20.5 (0.3, NE)	1.033 (0.245, 4.359)	0.9650
TEAE Leading to Treatment Discontinuation	13	2 (15.4)	NR (NE, NE)	17	6 (35.3)	NR (3.9, NE)	1.071 (0.177, 6.472)	0.9406

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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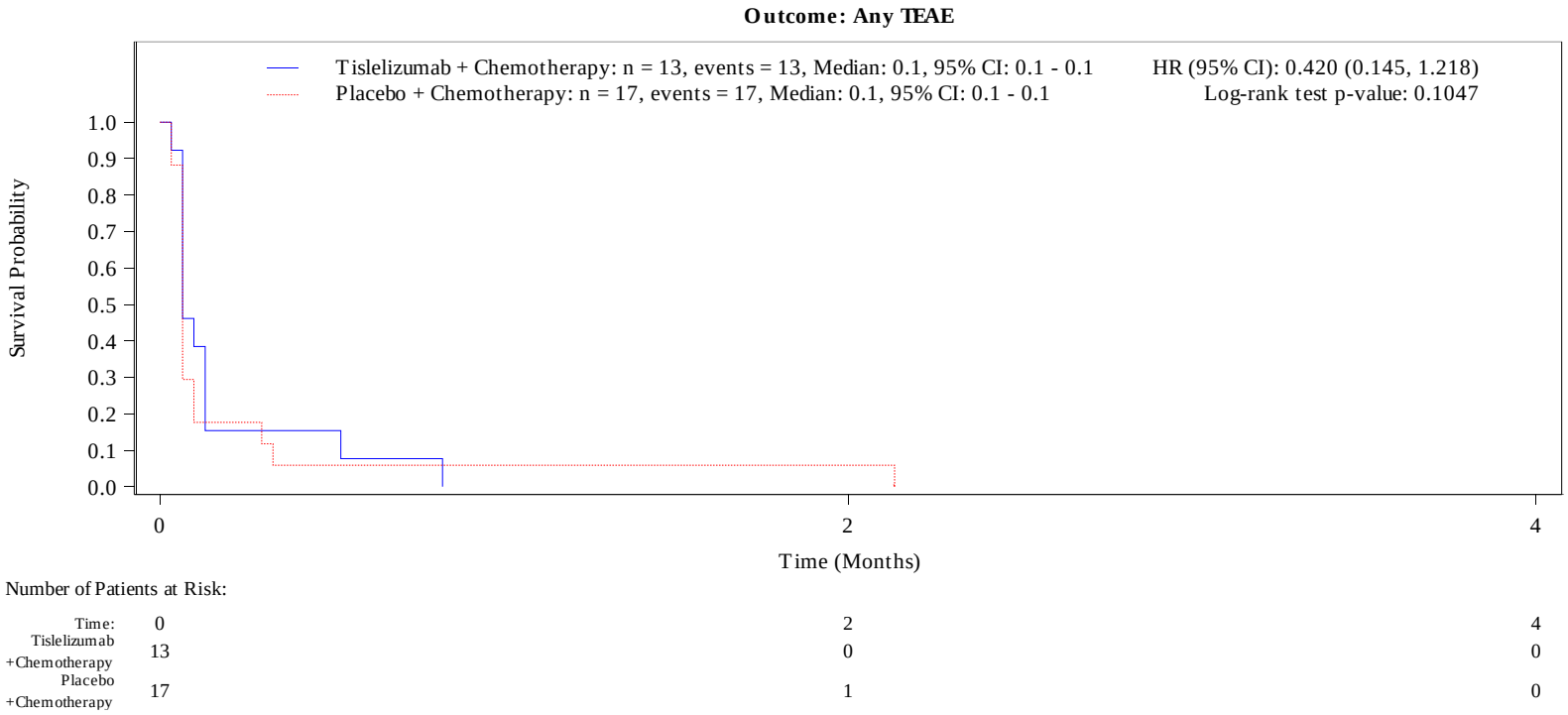
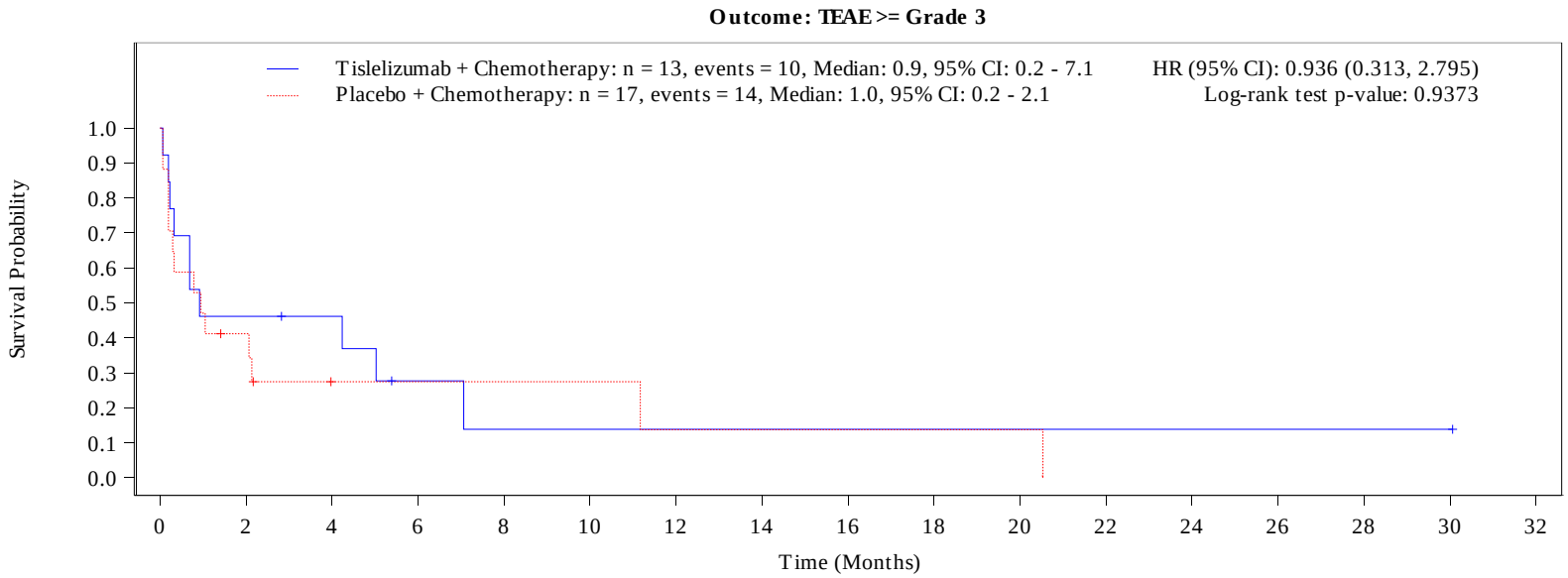
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-sa.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab +Chemotherapy	13	6	5	2	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	6	2	2	2	2	1	1	1	1	1	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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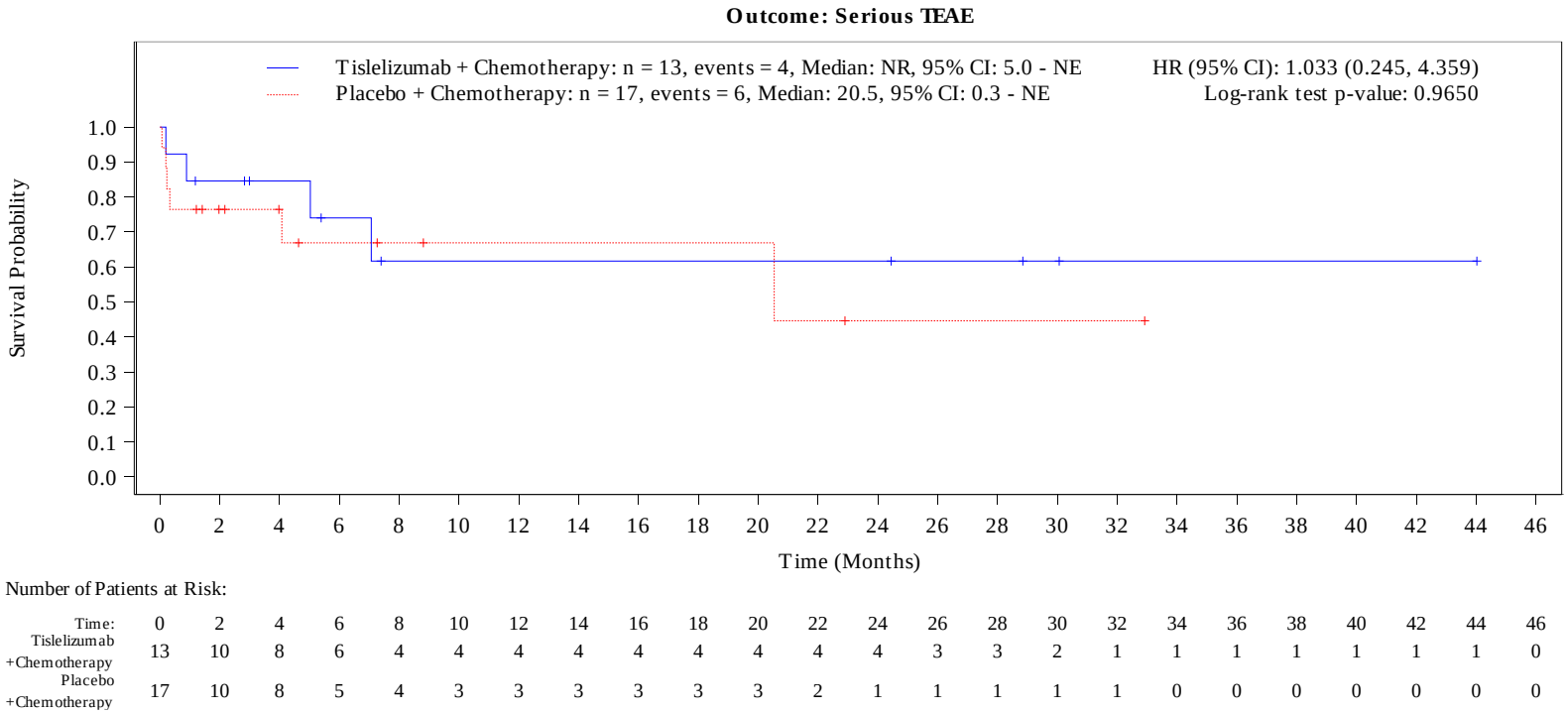
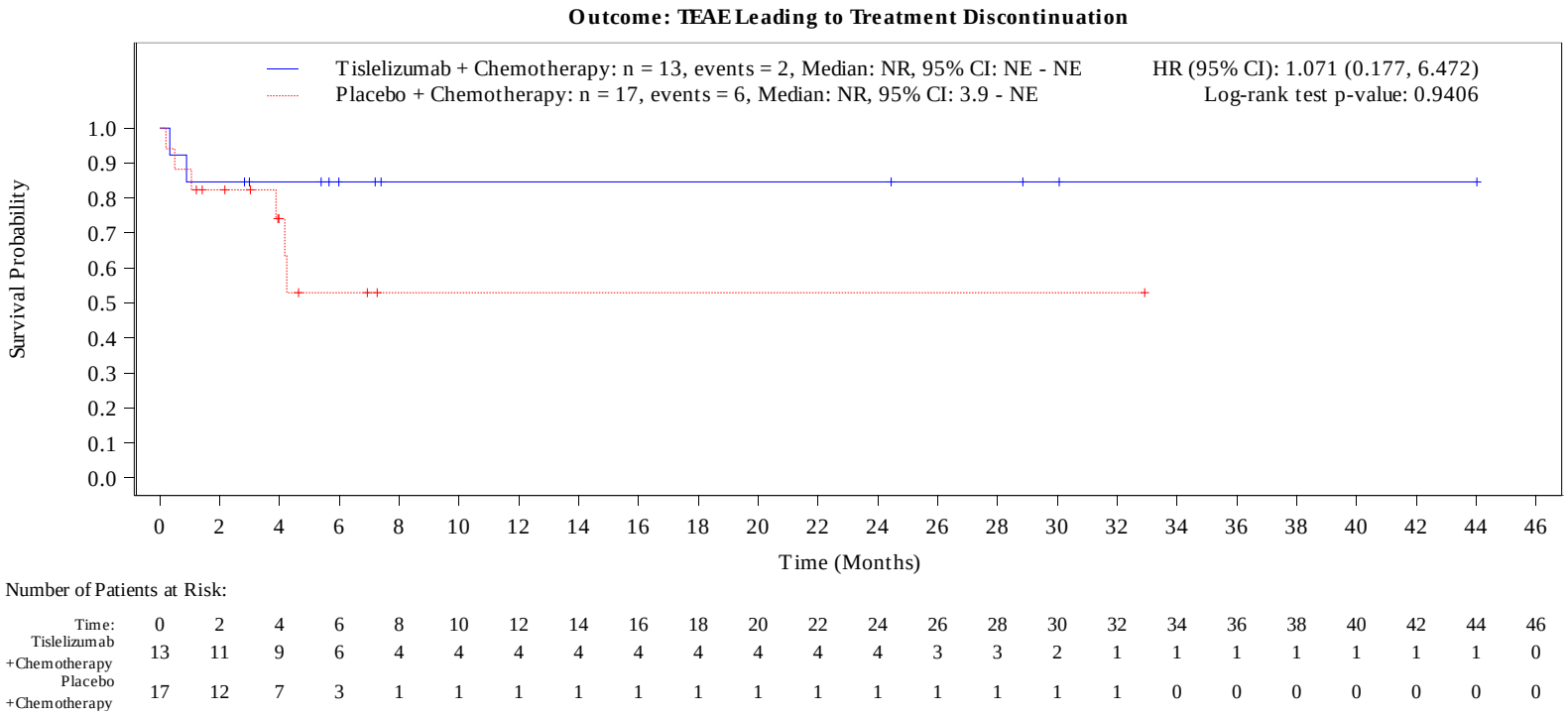
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-sa.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	7	3	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	9 (100.0)	0.1 (0.0, 0.5)	8	8 (100.0)	0.1 (0.0, 0.3)	0.890 (0.323, 2.454)	0.9808
Age >= 65	4	4 (100.0)	0.1 (0.1, NE)	9	9 (100.0)	0.1 (0.0, 0.1)	1.052 (0.294, 3.762)	0.9825
Interaction								0.8740

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	9 (100.0)	0.1 (0.1, 0.1)	11	11 (100.0)	0.1 (0.0, 0.1)	0.700 (0.275, 1.782)	0.3126
Female	4	4 (100.0)	0.1 (0.0, NE)	6	6 (100.0)	0.1 (0.1, NE)	0.971 (0.244, 3.866)	0.6939
Interaction								0.7957

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	7 (100.0)	0.1 (0.1, 0.1)	10	10 (100.0)	0.1 (0.0, 0.1)	0.275 (0.076, 0.991)	0.0233
1	6	6 (100.0)	0.1 (0.0, NE)	7	7 (100.0)	0.1 (0.1, 0.3)	1.474 (0.465, 4.673)	0.4652
Interaction								0.0384

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.1 (0.1, NE)	7	7 (100.0)	0.1 (0.0, 0.1)	0.468 (0.107, 2.057)	0.2016
No	9	9 (100.0)	0.1 (0.0, 0.5)	10	10 (100.0)	0.1 (0.1, 0.3)	0.986 (0.384, 2.530)	0.9089
Interaction								0.4597

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	6 (66.7)	4.2 (0.1, NE)	8	6 (75.0)	2.1 (0.3, NE)	1.002 (0.318, 3.157)	0.9984
Age >= 65	4	4 (100.0)	0.7 (0.2, NE)	9	8 (88.9)	0.2 (0.1, 1.0)	0.586 (0.153, 2.239)	0.4168
Interaction								0.4084

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	8 (88.9)	0.7 (0.2, NE)	11	9 (81.8)	1.0 (0.2, NE)	1.072 (0.397, 2.898)	0.8967
Female	4	2 (50.0)	4.2 (0.1, NE)	6	5 (83.3)	0.9 (0.1, NE)	0.445 (0.084, 2.365)	0.3195
Interaction								0.3981

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	0.7 (0.2, NE)	10	9 (90.0)	0.9 (0.1, 2.1)	0.887 (0.304, 2.593)	0.8329
1	6	4 (66.7)	2.6 (0.1, NE)	7	5 (71.4)	1.0 (0.1, NE)	0.831 (0.217, 3.183)	0.7833
Interaction								0.9489

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.5 (0.1, NE)	7	6 (85.7)	0.8 (0.1, NE)	1.481 (0.387, 5.667)	0.5460
No	9	6 (66.7)	4.2 (0.2, NE)	10	8 (80.0)	1.6 (0.2, NE)	0.654 (0.222, 1.924)	0.4392
Interaction								0.4606

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-tteae-subgrp.sas 21OCT2024 09:21 t-14-3-1-2-1-1-s-tteae-subgrp-pop1-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-tteae-subgrp.sas 21OCT2024 09:21 t-14-3-1-2-1-1-s-tteae-subgrp-pop1-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	3 (33.3)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	1 (14.3)	--	--	--
No	9	1 (11.1)	--	10	5 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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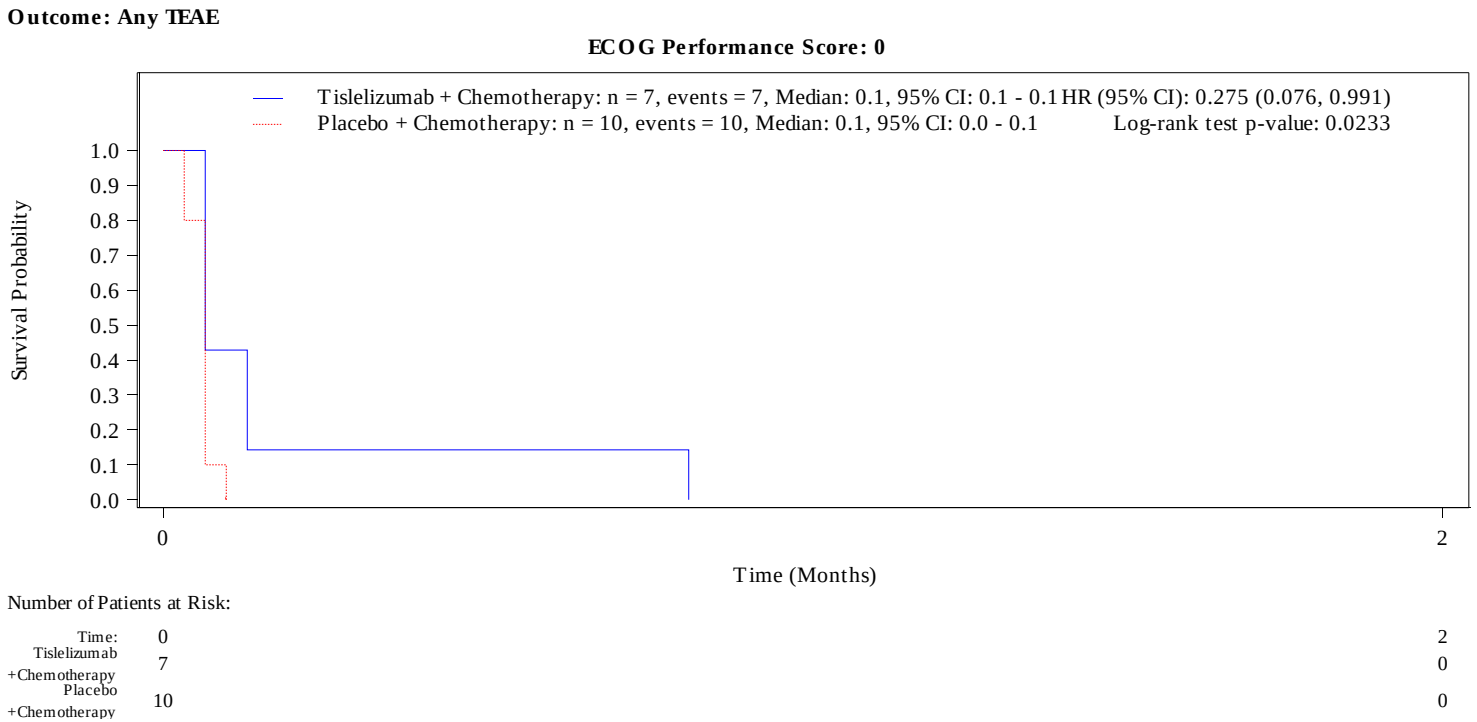
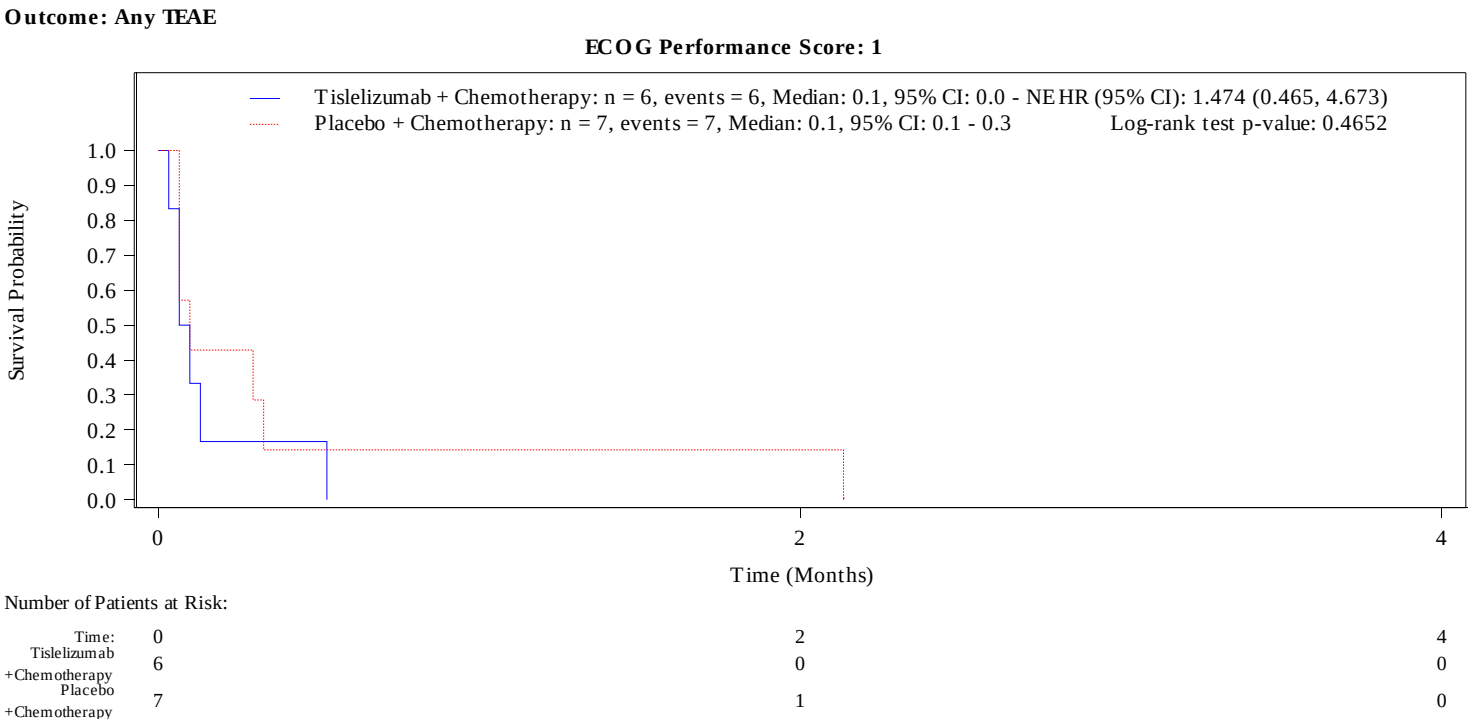
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	8 (61.5)	1.4 (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	4.057 (0.957, 17.200)	0.0451
Anaemia	13	6 (46.2)	NR (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	3.407 (0.772, 15.033)	0.0923
Leukopenia	13	2 (15.4)	NR (1.3, NE)	17	1 (5.9)	NR (NE, NE)	2.442 (0.202, 29.535)	0.4712
Neutropenia	13	3 (23.1)	NR (1.4, NE)	17	3 (17.6)	NR (5.0, NE)	2.435 (0.367, 16.158)	0.3451
Endocrine disorders	13	2 (15.4)	NR (4.2, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3008
Gastrointestinal disorders	13	11 (84.6)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.2)	1.027 (0.408, 2.589)	0.9873

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Constipation	13	9 (69.2)	0.8 (0.1, NE)	17	9 (52.9)	0.9 (0.1, NE)	0.606 (0.201, 1.833)	0.4122
Diarrhoea	13	4 (30.8)	36.1 (3.5, NE)	17	7 (41.2)	15.7 (0.8, NE)	1.092 (0.216, 5.529)	0.9152
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (20.5, NE)	NE (NE, NE)	NE
Nausea	13	5 (38.5)	NR (0.1, NE)	17	9 (52.9)	0.8 (0.1, NE)	0.775 (0.237, 2.530)	0.6705
Stomatitis	13	5 (38.5)	NR (0.2, NE)	17	7 (41.2)	NR (0.4, NE)	1.091 (0.260, 4.580)	0.9449
General disorders and administration site conditions	13	7 (53.8)	1.7 (0.1, NE)	17	12 (70.6)	0.2 (0.1, NE)	0.588 (0.216, 1.600)	0.3153

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Asthenia	13	1 (7.7)	NR (NE, NE)	17	4 (23.5)	NR (1.2, NE)	0.592 (0.062, 5.654)	0.6573
Fatigue	13	2 (15.4)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.493 (0.078, 3.128)	0.4453
Generalised oedema	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Malaise	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.345 (0.034, 3.496)	0.3486
Pyrexia	13	2 (15.4)	NR (3.9, NE)	17	4 (23.5)	NR (12.3, NE)	1.204 (0.161, 8.988)	0.8560
Infections and infestations	13	5 (38.5)	9.4 (1.5, NE)	17	5 (29.4)	17.5 (7.2, NE)	3.558 (0.574, 22.063)	0.1560

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia	13	2 (15.4)	NR (11.9, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urinary tract infection	13	1 (7.7)	NR (3.3, NE)	17	2 (11.8)	NR (15.1, NE)	>999.99 (0.000, NE)	0.4497
Injury, poisoning and procedural complications	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336
Fall	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	13	10 (76.9)	0.7 (0.5, 4.2)	17	8 (47.1)	5.1 (0.5, NE)	1.161 (0.387, 3.481)	0.7769
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.243 (0.022, 2.711)	0.2283

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood creatinine increased	13	2 (15.4)	NR (1.4, NE)	17	2 (11.8)	NR (4.0, NE)	0.762 (0.100, 5.803)	0.7921
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.406 (0.089, 1.851)	0.2311
Platelet count decreased	13	4 (30.8)	NR (2.9, NE)	17	1 (5.9)	32.9 (NE, NE)	>999.99 (0.000, NE)	0.0757
Weight decreased	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (5.1, NE)	0.712 (0.063, 8.022)	0.7822
White blood cell count decreased	13	4 (30.8)	NR (4.2, NE)	17	6 (35.3)	NR (1.6, NE)	0.204 (0.039, 1.080)	0.0415

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	13	10 (76.9)	1.8 (0.5, NE)	17	9 (52.9)	6.5 (0.5, NE)	1.352 (0.454, 4.025)	0.5963
Decreased appetite	13	7 (53.8)	6.7 (0.8, NE)	17	4 (23.5)	NR (6.7, NE)	2.575 (0.588, 11.282)	0.1983
Hyperglycaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1614
Hyperuricaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1086
Hypokalaemia	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.555 (0.056, 5.515)	0.6104
Hyponatraemia	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.614 (0.052, 7.308)	0.6974
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1614

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	14.6 (9.3, NE)	2.236 (0.111, 44.877)	0.5930
Nervous system disorders	13	2 (15.4)	NR (5.4, NE)	17	9 (52.9)	3.3 (0.3, NE)	0.211 (0.041, 1.086)	0.0461
Dysgeusia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Peripheral sensory neuropathy	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.3, NE)	0.700 (0.100, 4.925)	0.7195
Psychiatric disorders	13	2 (15.4)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Insomnia	13	1 (7.7)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072
Renal and urinary disorders	13	1 (7.7)	NR (4.7, NE)	17	5 (29.4)	NR (2.8, NE)	0.176 (0.019, 1.637)	0.0892
Chronic kidney disease	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Renal impairment	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.2, NE)	0.000 (0.000, NE)	0.0564
Respiratory, thoracic and mediastinal disorders	13	6 (46.2)	6.2 (1.1, NE)	17	9 (52.9)	2.4 (0.2, NE)	0.793 (0.248, 2.534)	0.7245
Cough	13	2 (15.4)	NR (16.5, NE)	17	1 (5.9)	NR (NE, NE)	1.768 (0.075, 41.454)	0.7221

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hiccups	13	2 (15.4)	NR (NE, NE)	17	4 (23.5)	NR (2.4, NE)	0.283 (0.049, 1.624)	0.1387
Pneumonia aspiration	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	21.4 (21.4, NE)	1.000 (0.053, 18.915)	1.0000
Skin and subcutaneous tissue disorders	13	6 (46.2)	6.9 (1.2, NE)	17	7 (41.2)	12.9 (1.2, NE)	0.932 (0.251, 3.464)	0.8956
Alopecia	13	2 (15.4)	NR (3.3, NE)	17	1 (5.9)	NR (NE, NE)	2.631 (0.211, 32.795)	0.4396
Palmar-plantar erythrodysaesthesia syndrome	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.6, NE)	0.000 (0.000, NE)	0.3173
Pruritus	13	3 (23.1)	NR (4.7, NE)	17	1 (5.9)	NR (12.9, NE)	>999.99 (0.000, NE)	0.4190

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Rash	13	2 (15.4)	NR (6.9, NE)	17	1 (5.9)	NR (NE, NE)	1.699 (0.135, 21.378)	0.6790
Vascular disorders	13	2 (15.4)	NR (5.4, NE)	17	4 (23.5)	NR (3.5, NE)	0.181 (0.019, 1.744)	0.1049
Flushing	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0673

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	2 (15.4)	NR (1.6, NE)	17	4 (23.5)	NR (4.0, NE)	0.819 (0.123, 5.460)	0.8364
Anaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.0, NE)	0.000 (0.000, NE)	0.0859
Leukopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Lymphopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Neutropenia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (5.0, NE)	0.000 (0.000, NE)	0.2008
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Eye disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859
Cataract	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	5 (29.4)	NR (1.1, NE)	0.424 (0.042, 4.291)	0.4580
Acquired soft palate fissure	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Diarrhoea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.630 (0.049, 8.140)	0.7214

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	13	2 (15.4)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0325
Asthenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Fatigue	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3173

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	13	2 (15.4)	NR (5.0, NE)	17	1 (5.9)	NR (NE, NE)	7.027 (0.614, 80.430)	0.0717
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Investigations	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.376 (0.084, 1.686)	0.1984
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4795
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	4 (23.5)	NR (2.1, NE)	0.844 (0.197, 3.605)	0.8183
White blood cell count decreased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.4, NE)	0.000 (0.000, NE)	0.1499
Metabolism and nutrition disorders	13	3 (23.1)	NR (1.8, NE)	17	5 (29.4)	11.2 (4.1, NE)	0.737 (0.126, 4.302)	0.7342
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	3.162 (0.184, 54.388)	0.4054
Hyperkalaemia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Hypoglycaemia	13	1 (7.7)	NR (17.2, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.1, NE)	0.000 (0.000, NE)	0.1439
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (11.2, NE)	0.000 (0.000, NE)	0.4795
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Skin and subcutaneous tissue disorders	13	2 (15.4)	41.2 (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Rash	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Skin toxicity	13	1 (7.7)	41.2 (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (20.5, NE)	0.821 (0.062, 10.940)	0.8814
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Nausea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Asthenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Infections and infestations	13	3 (23.1)	NR (1.5, NE)	17	1 (5.9)	NR (NE, NE)	7.889 (0.745, 83.509)	0.0530
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Pulmonary tuberculosis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Metabolism and nutrition disorders	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	1.000 (0.081, 12.270)	1.0000
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	0.000 (0.000, NE)	0.2253
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Nervous system disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Presyncope	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Patients with at Least One TEAE Leading to Any Treatment Discontinuation	2 (15.4)	6 (35.3)
General disorders and administration site conditions	1 (7.7)	0 (0.0)
Asthenia	1 (7.7)	0 (0.0)
Metabolism and nutrition disorders	1 (7.7)	0 (0.0)
Decreased appetite	1 (7.7)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (7.7)	0 (0.0)
Rash	1 (7.7)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	1 (5.9)
Acquired soft palate fissure	0 (0.0)	1 (5.9)

Source: ADSL, ADAE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.
Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Infections and infestations	0 (0.0)	1 (5.9)
Pneumonia	0 (0.0)	1 (5.9)
Nervous system disorders	0 (0.0)	1 (5.9)
Peripheral sensory neuropathy	0 (0.0)	1 (5.9)
Renal and urinary disorders	0 (0.0)	3 (17.6)
Chronic kidney disease	0 (0.0)	1 (5.9)
Renal impairment	0 (0.0)	2 (11.8)

Source: ADSL, ADAE. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.
Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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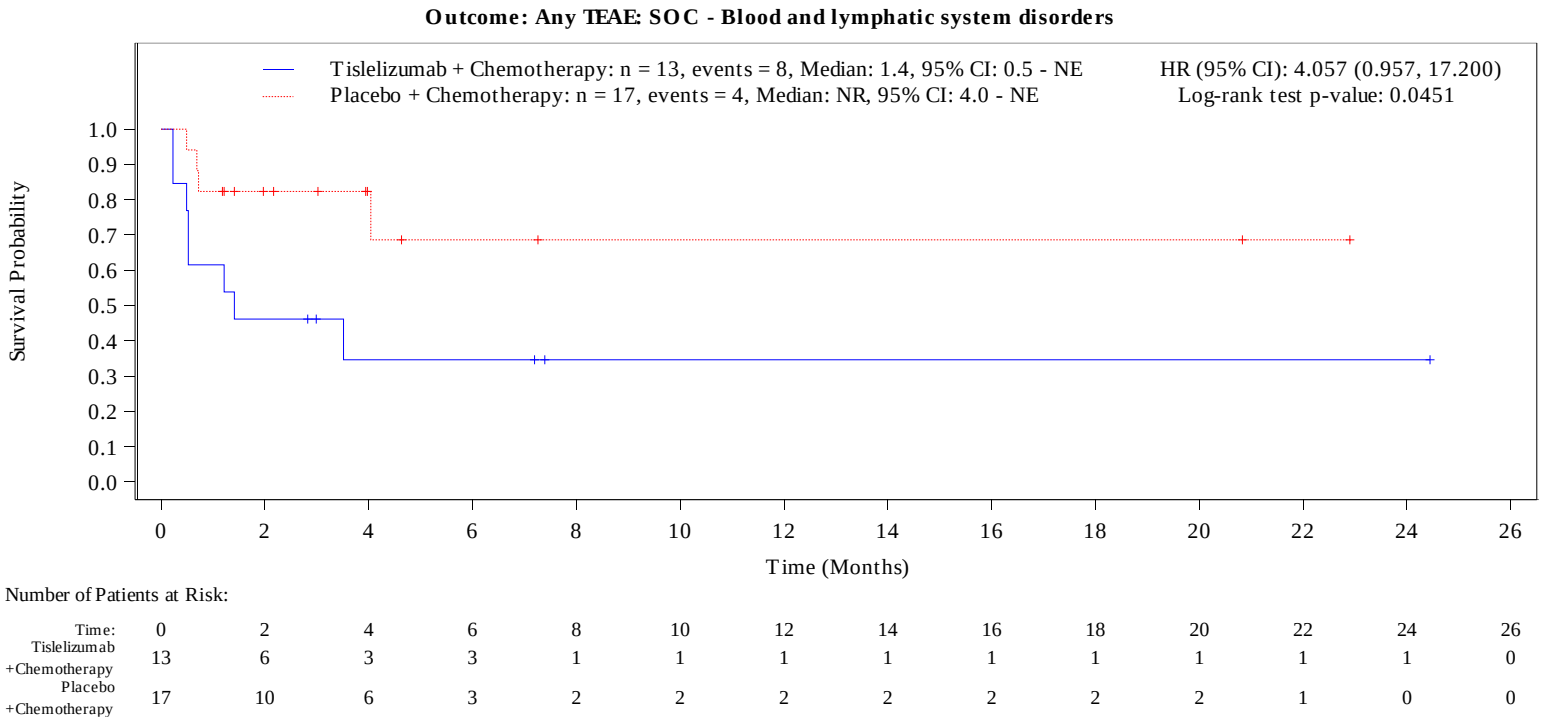
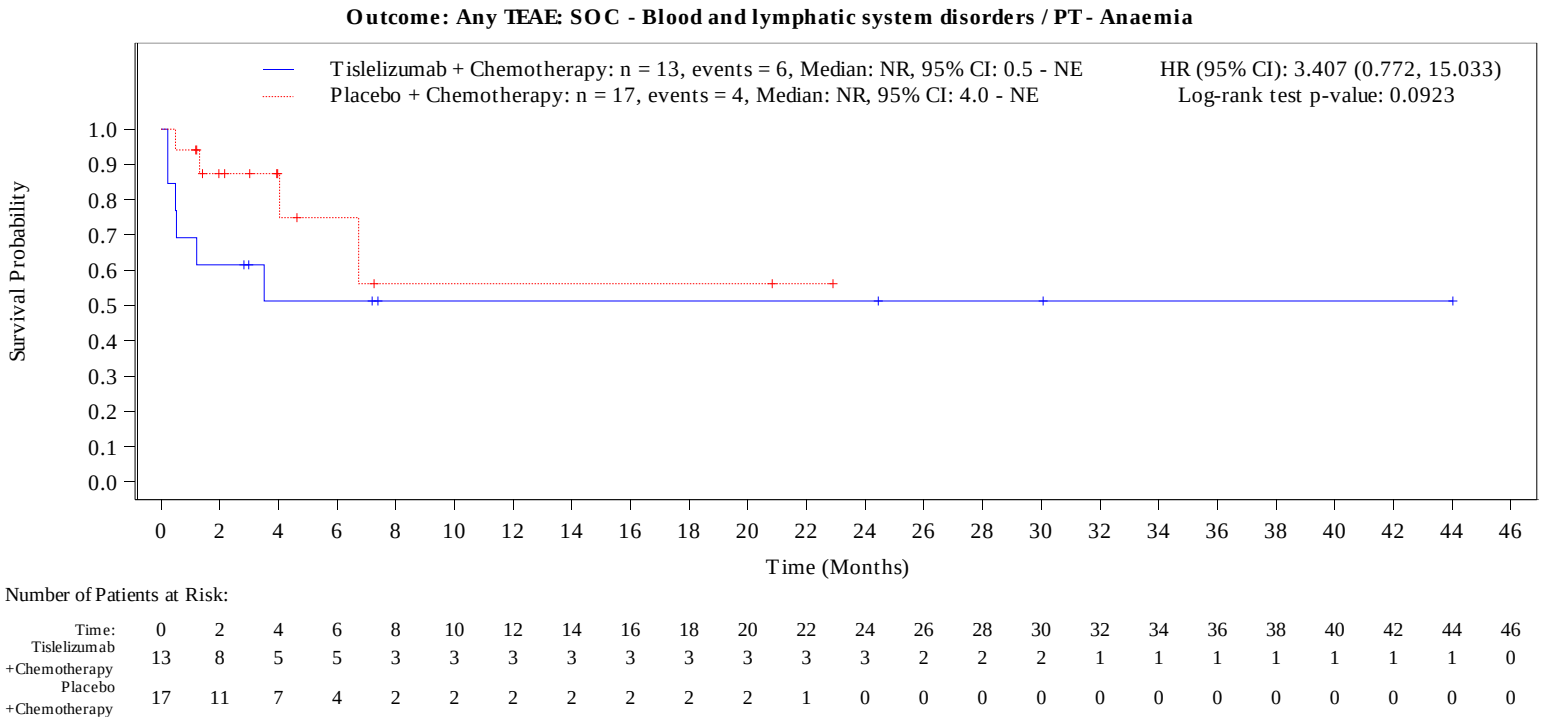
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-2-km-aesocpt-teae-pop1-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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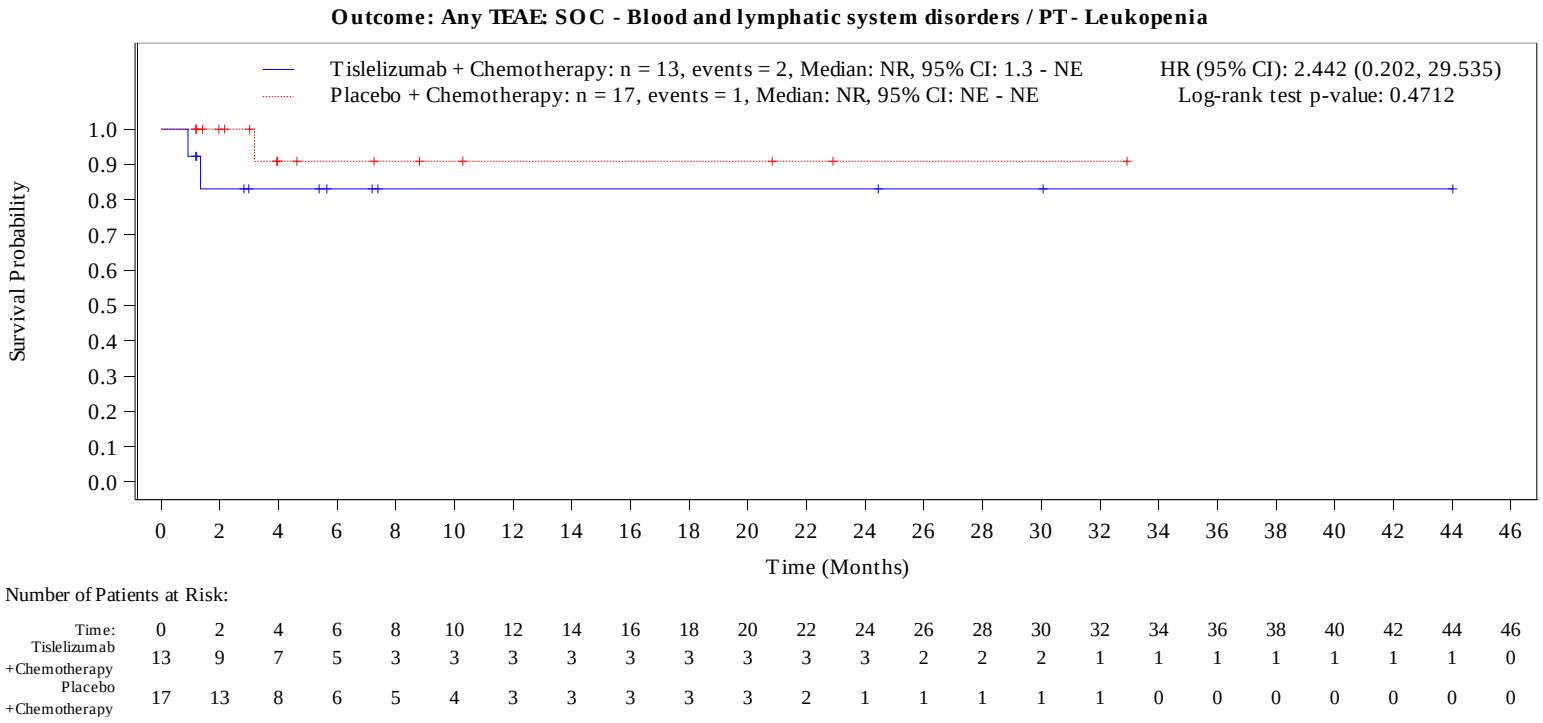
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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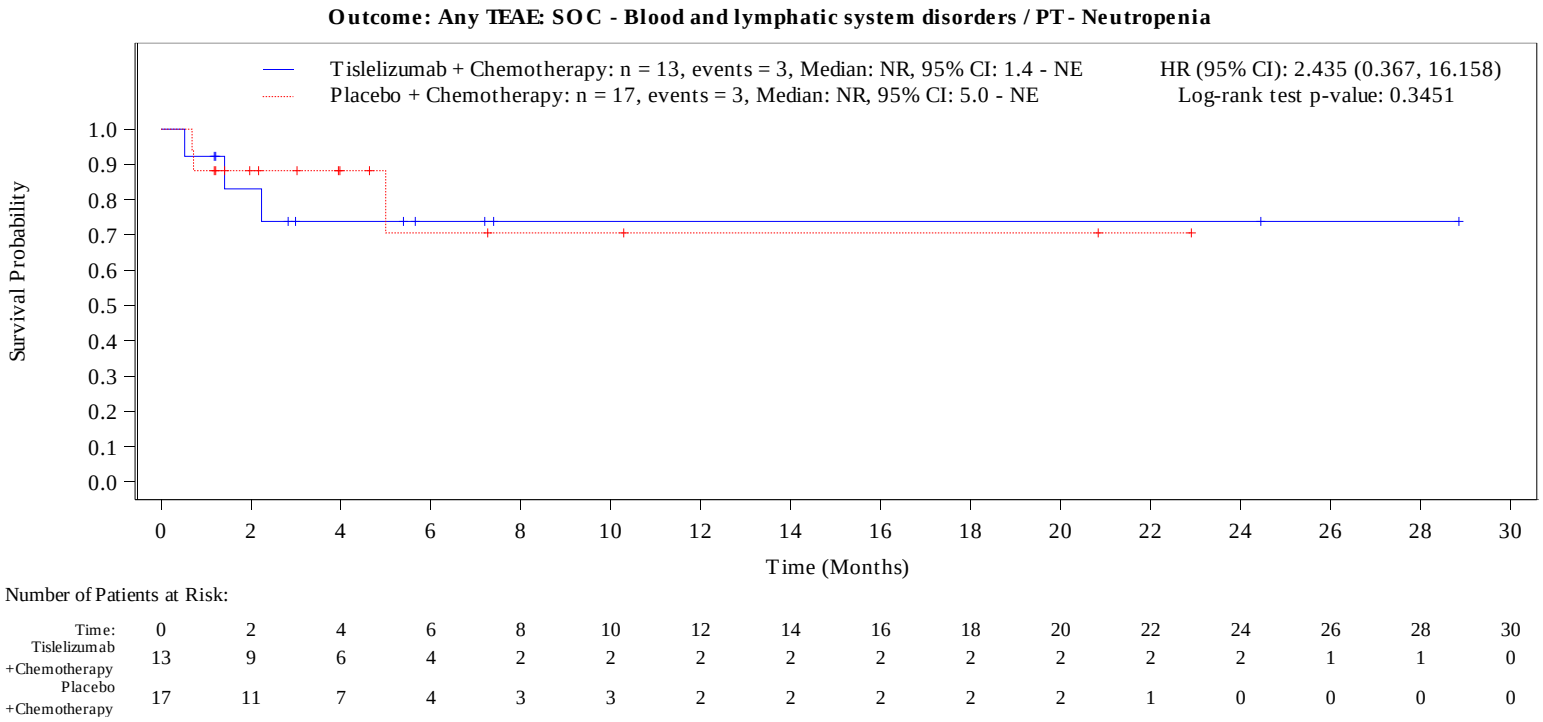
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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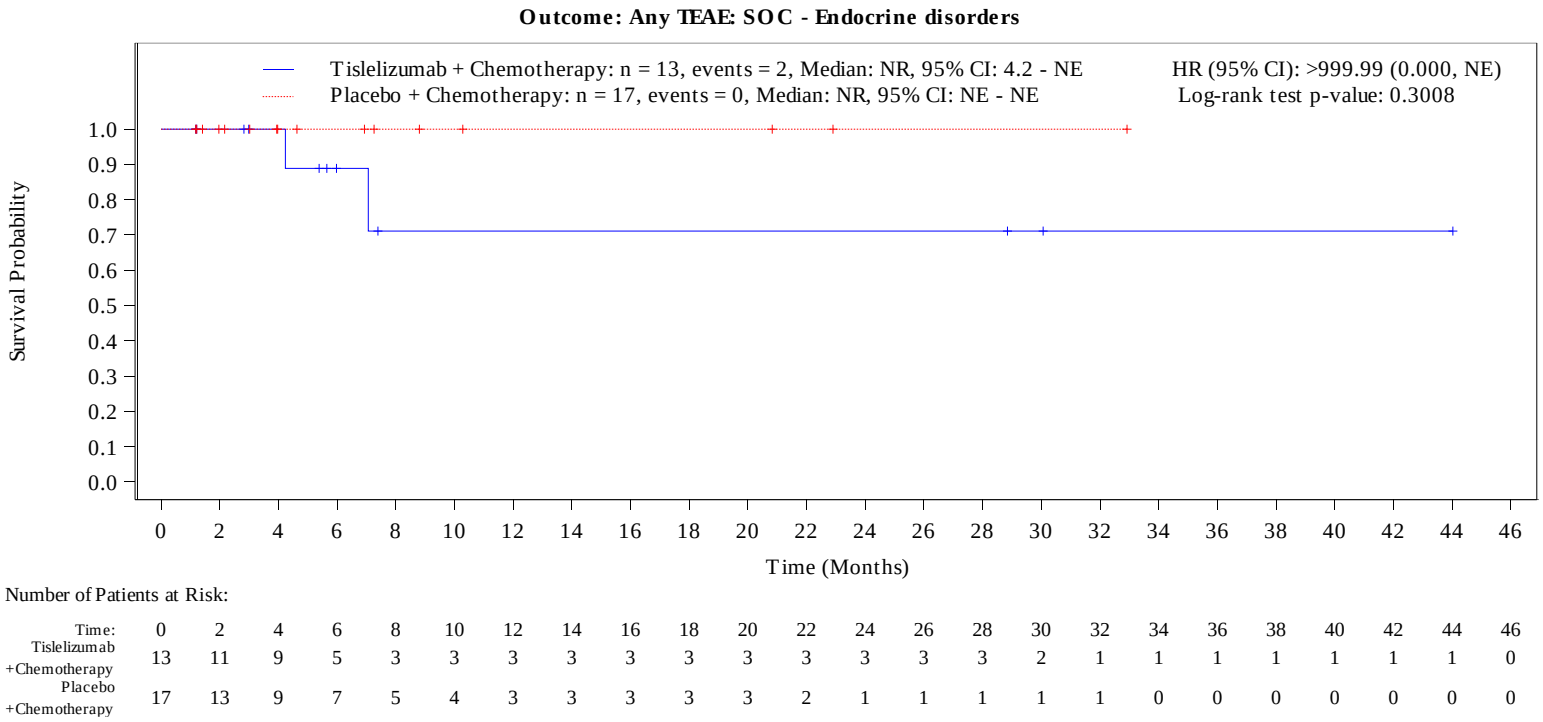

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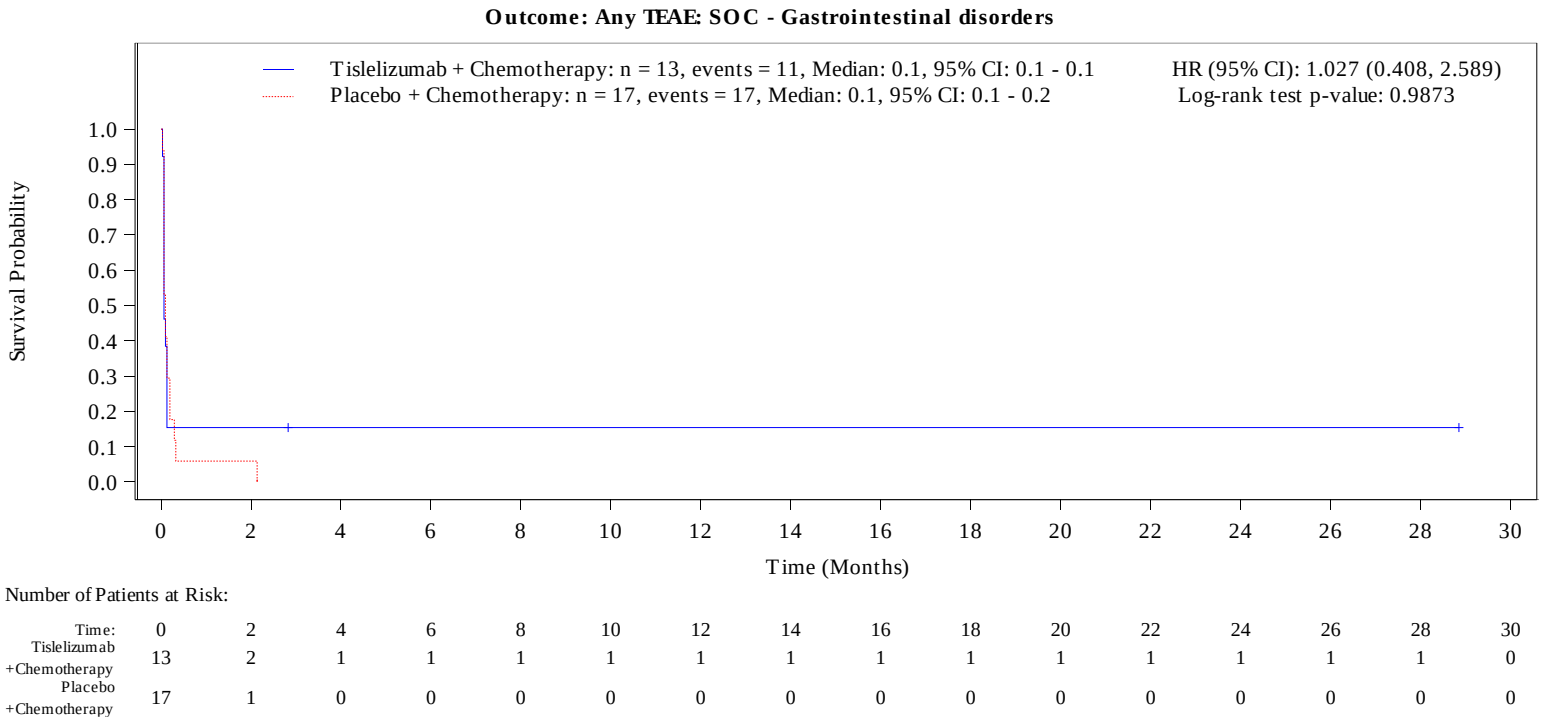

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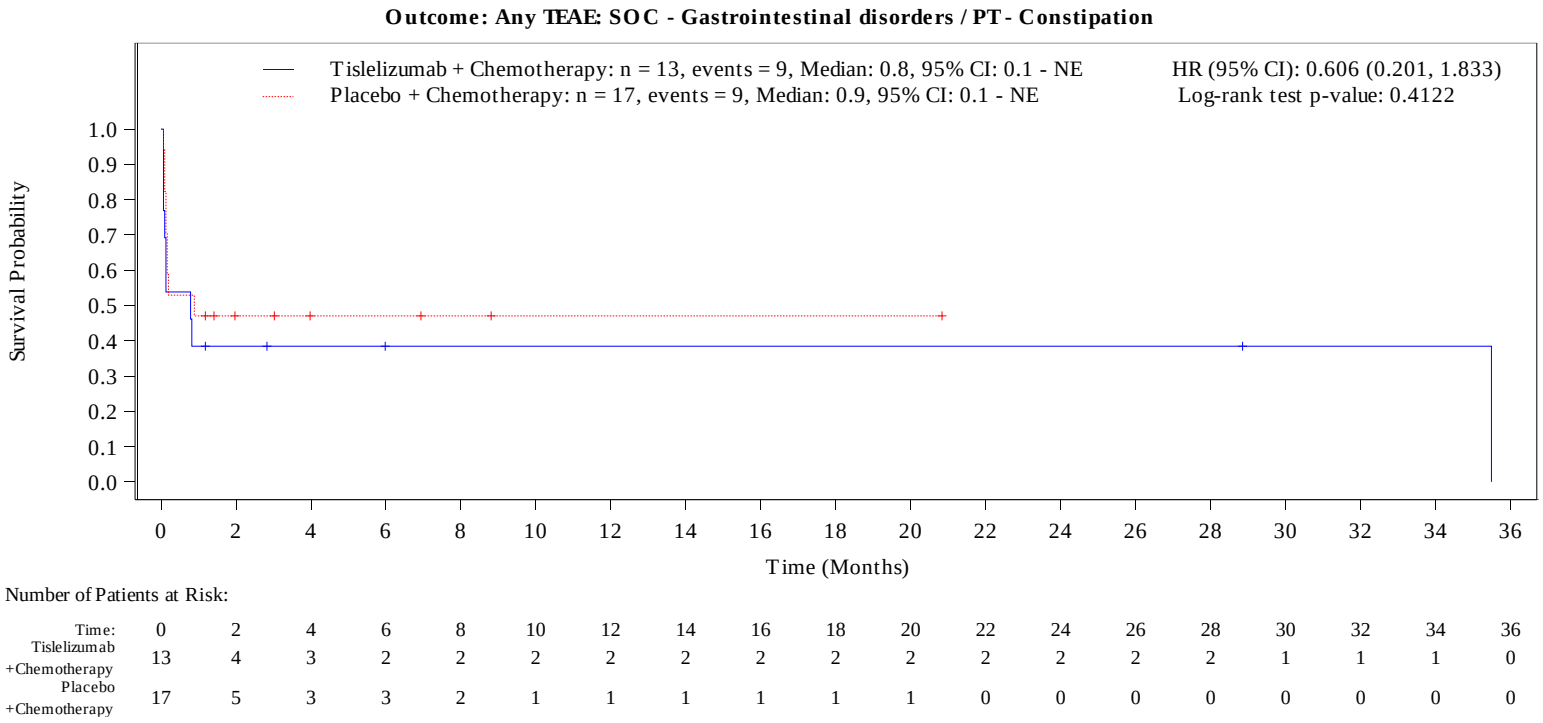

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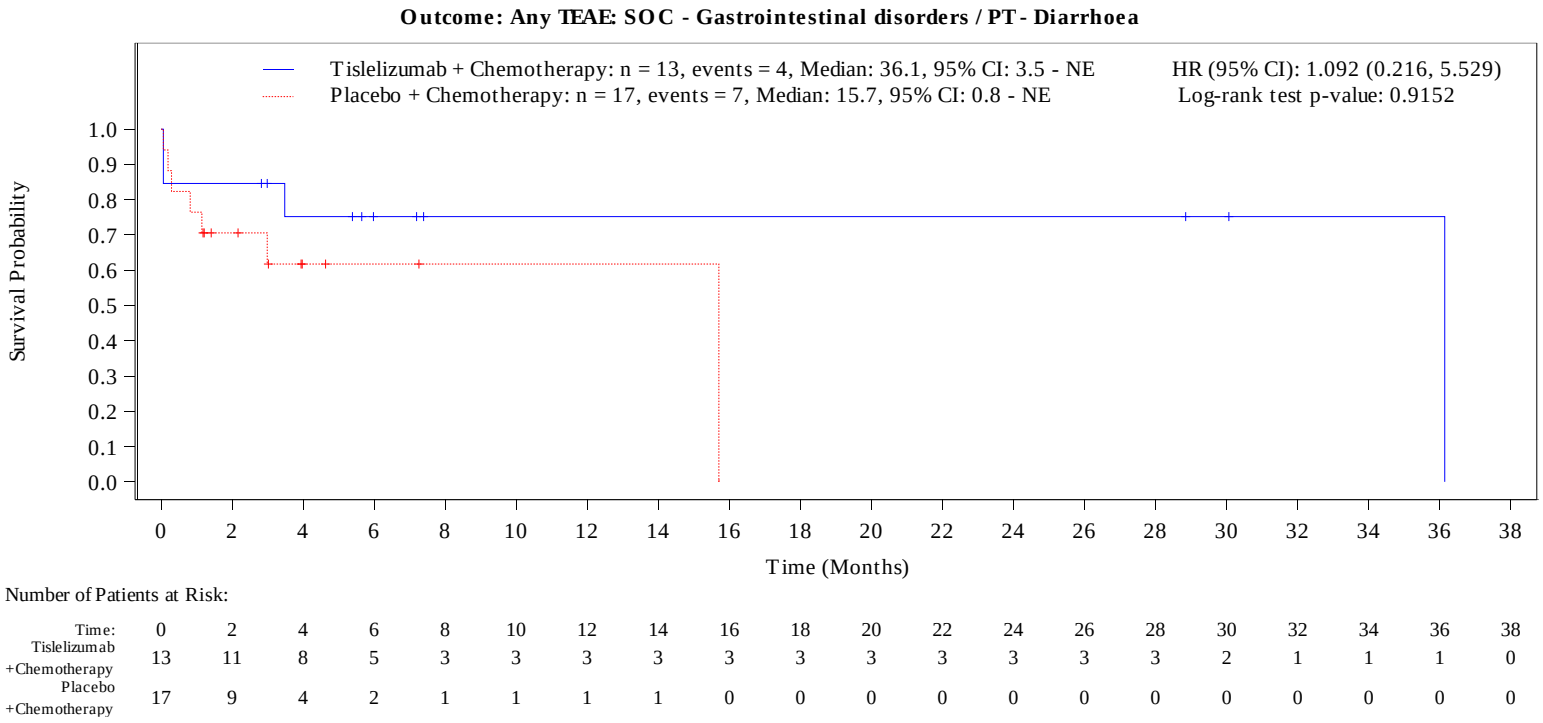

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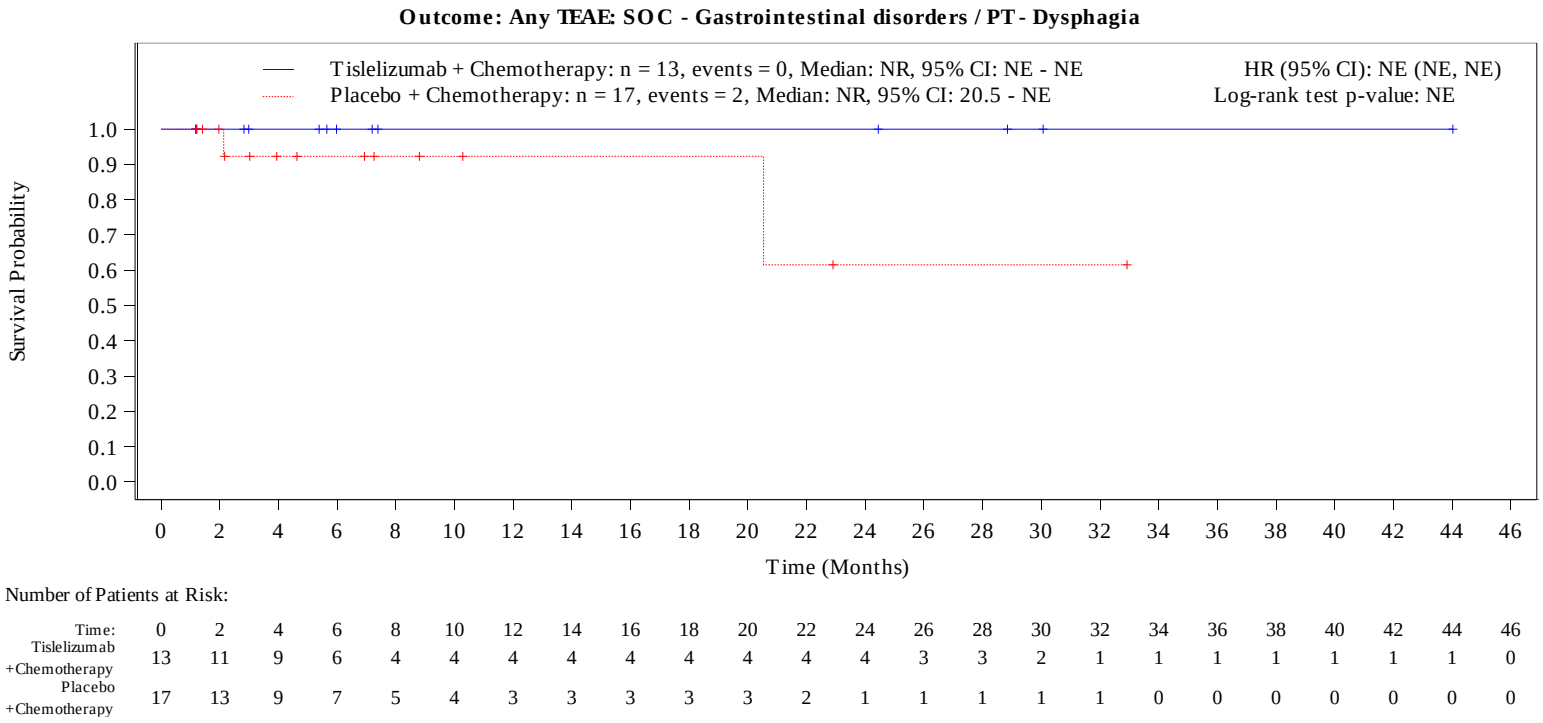

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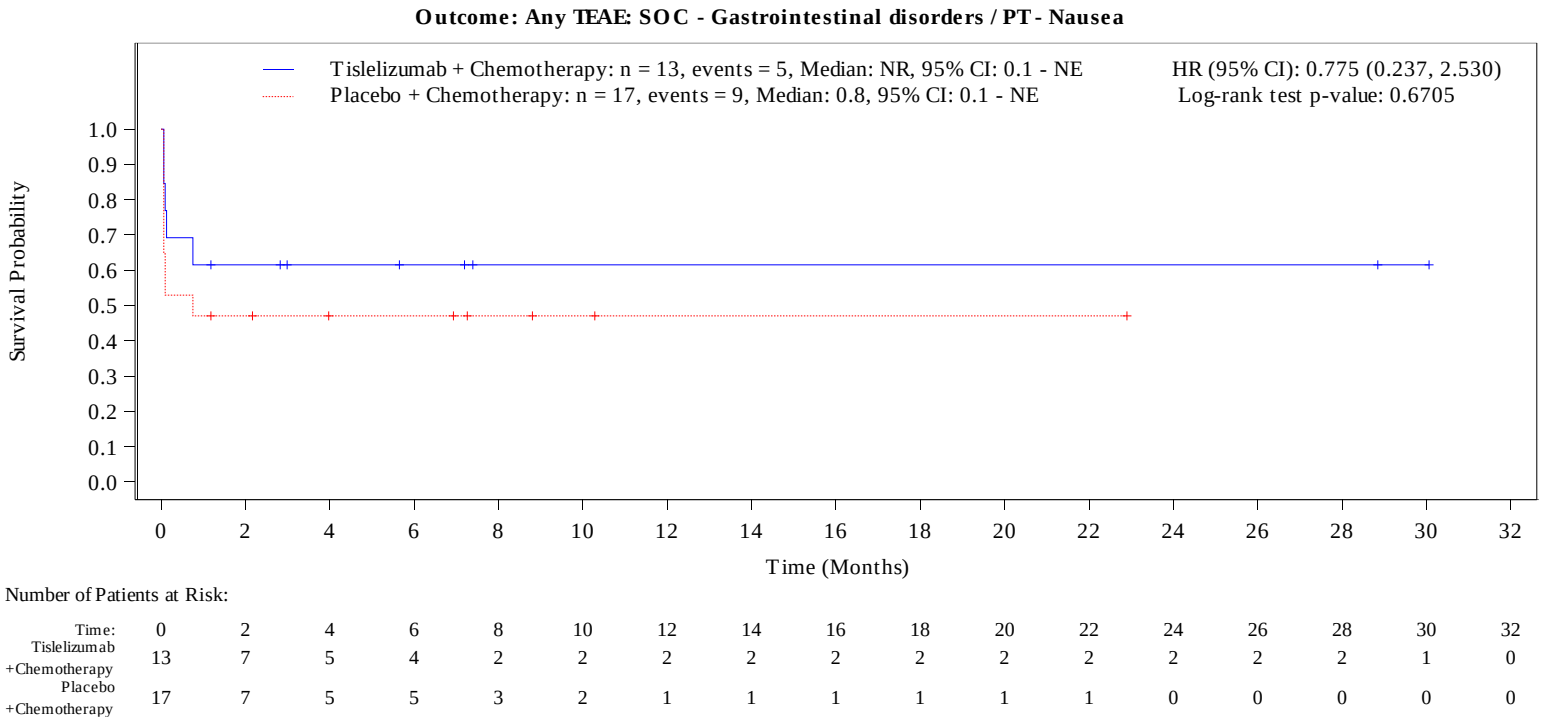

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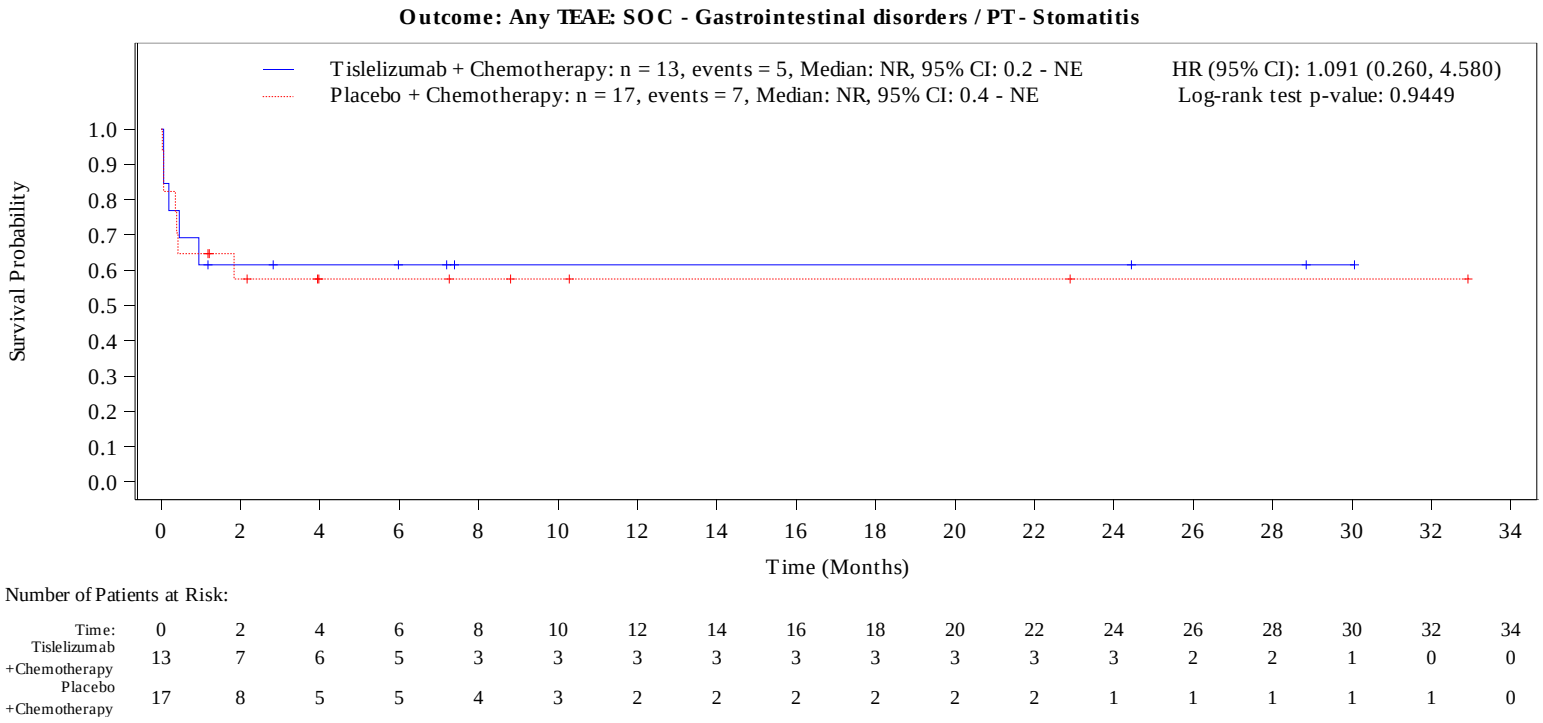

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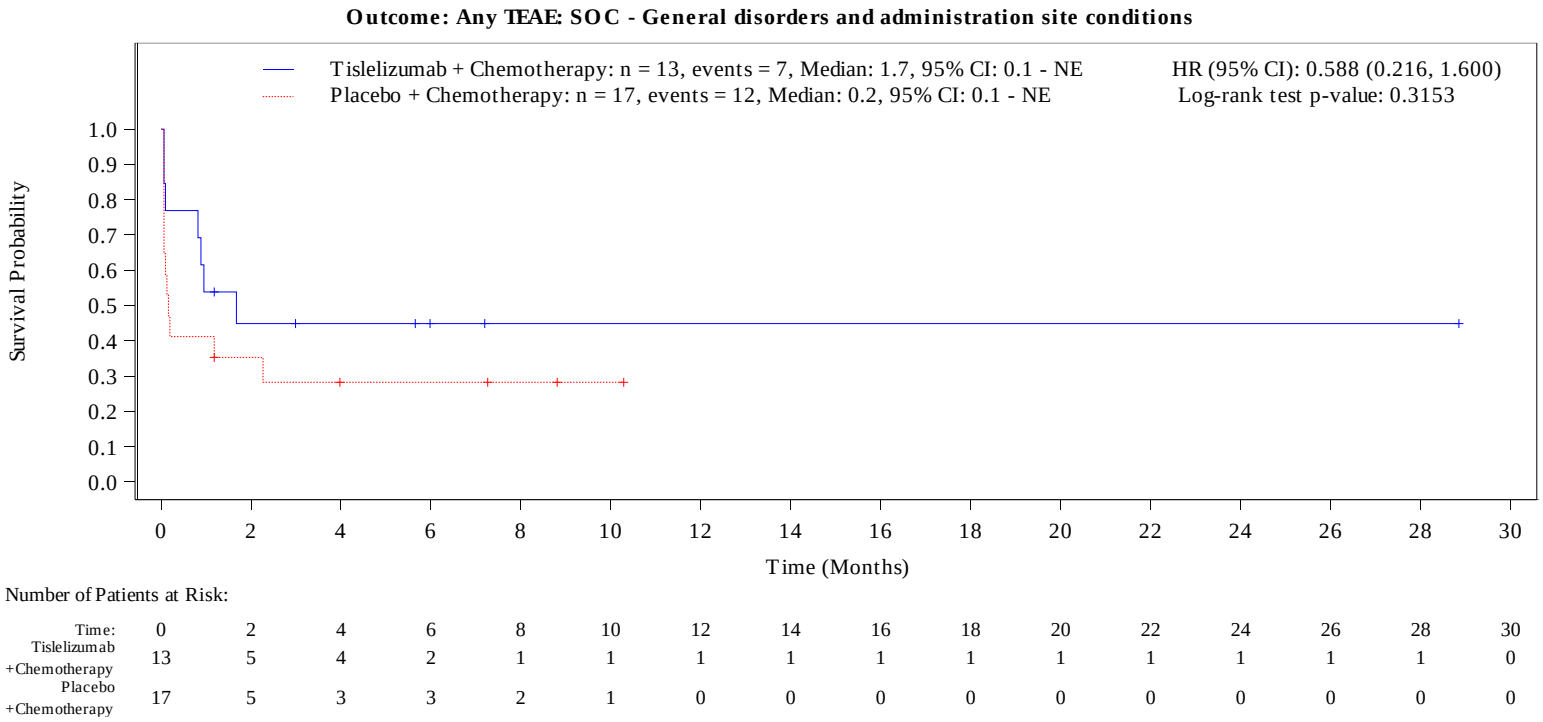

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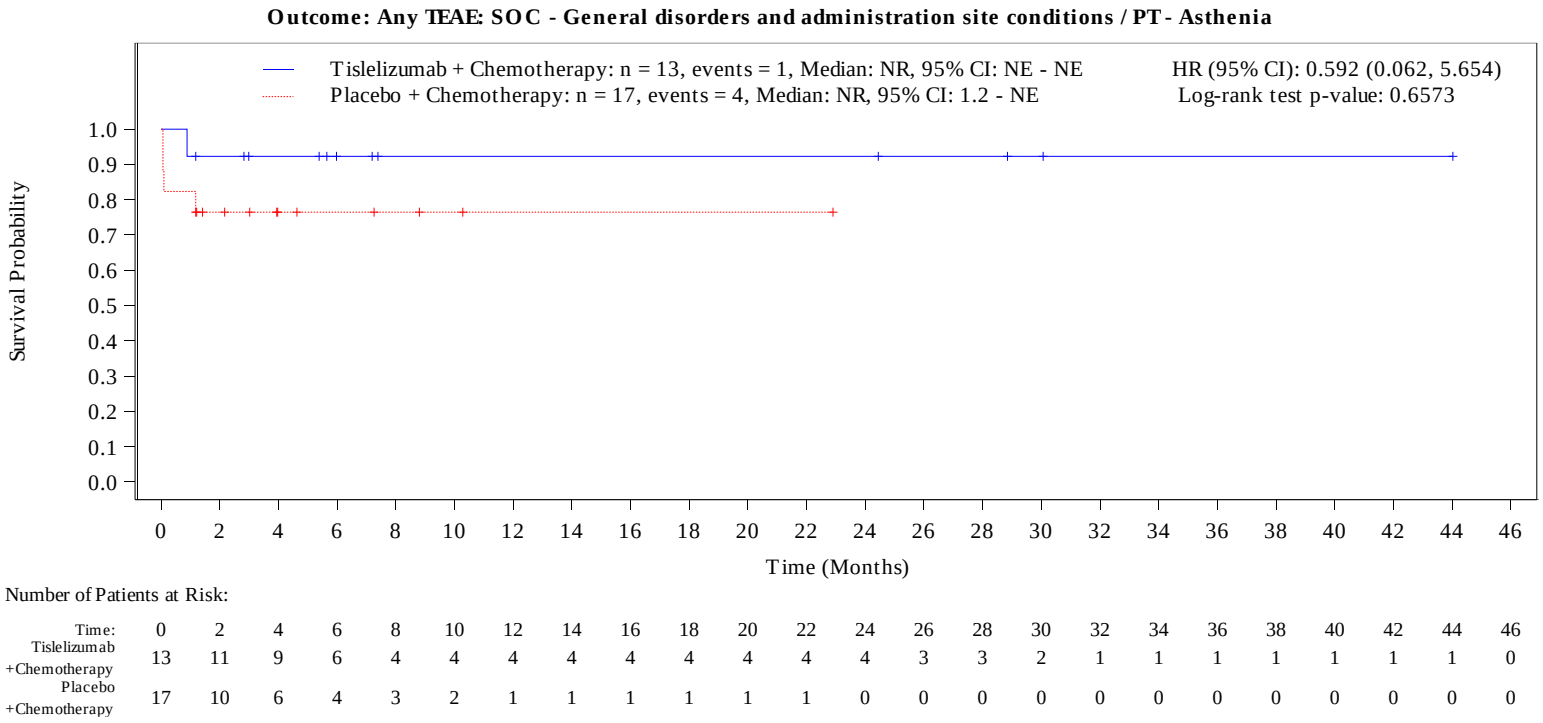

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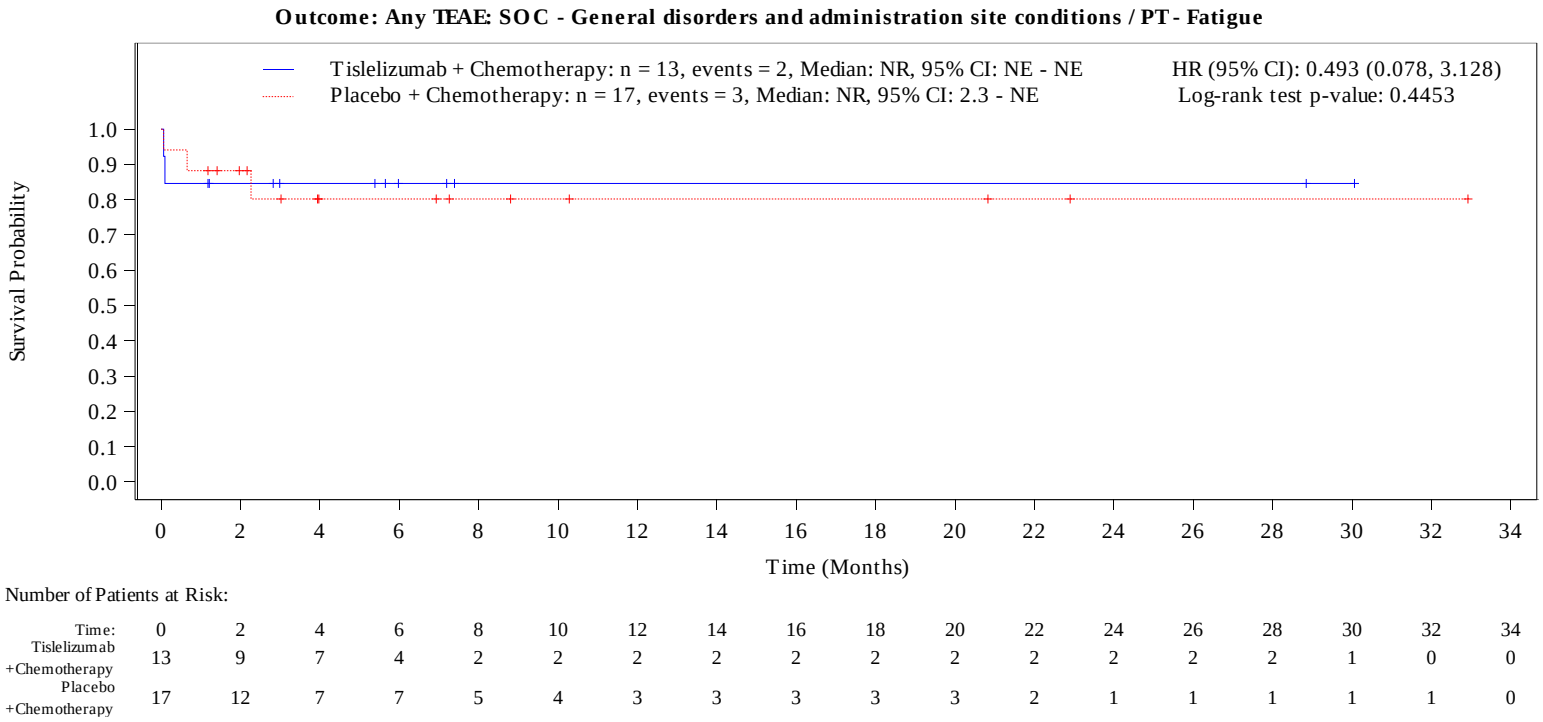

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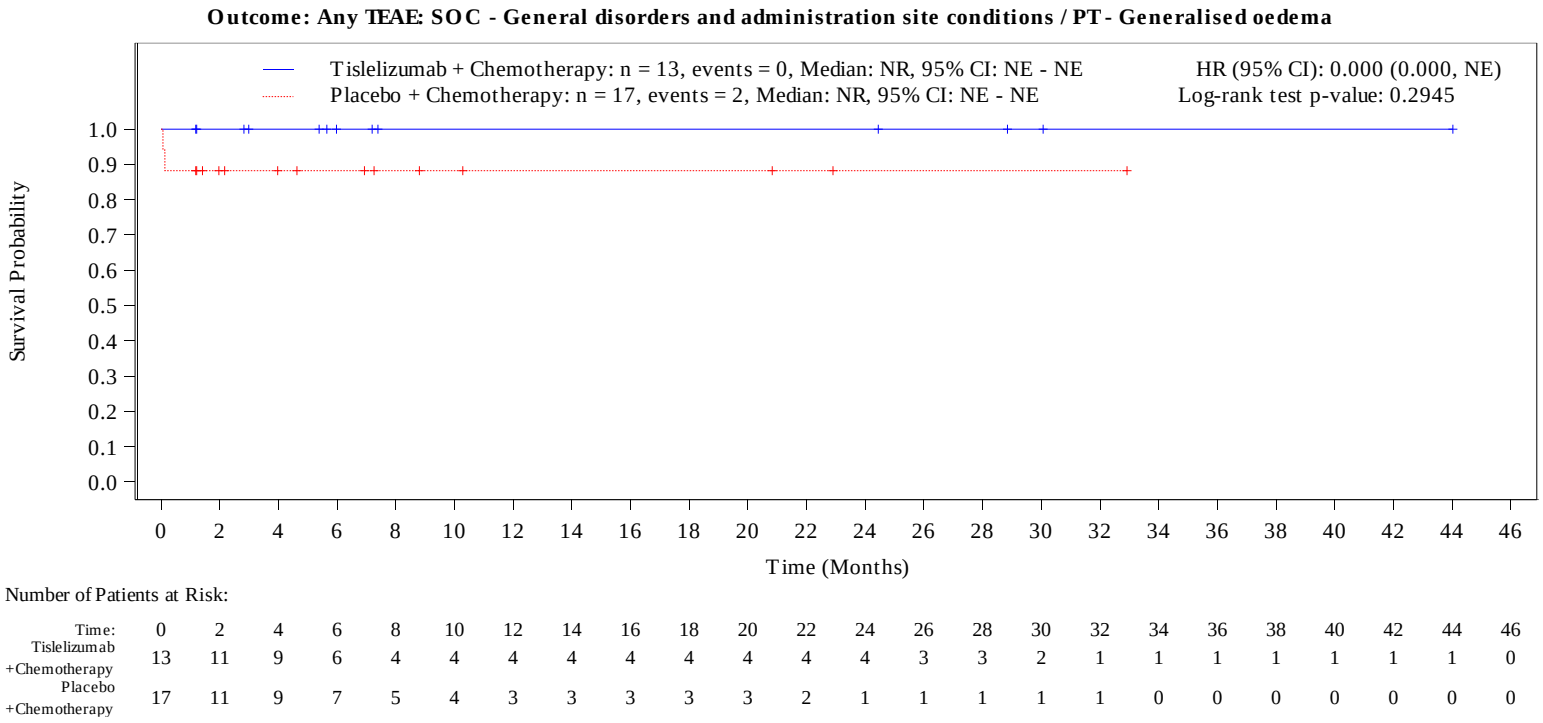

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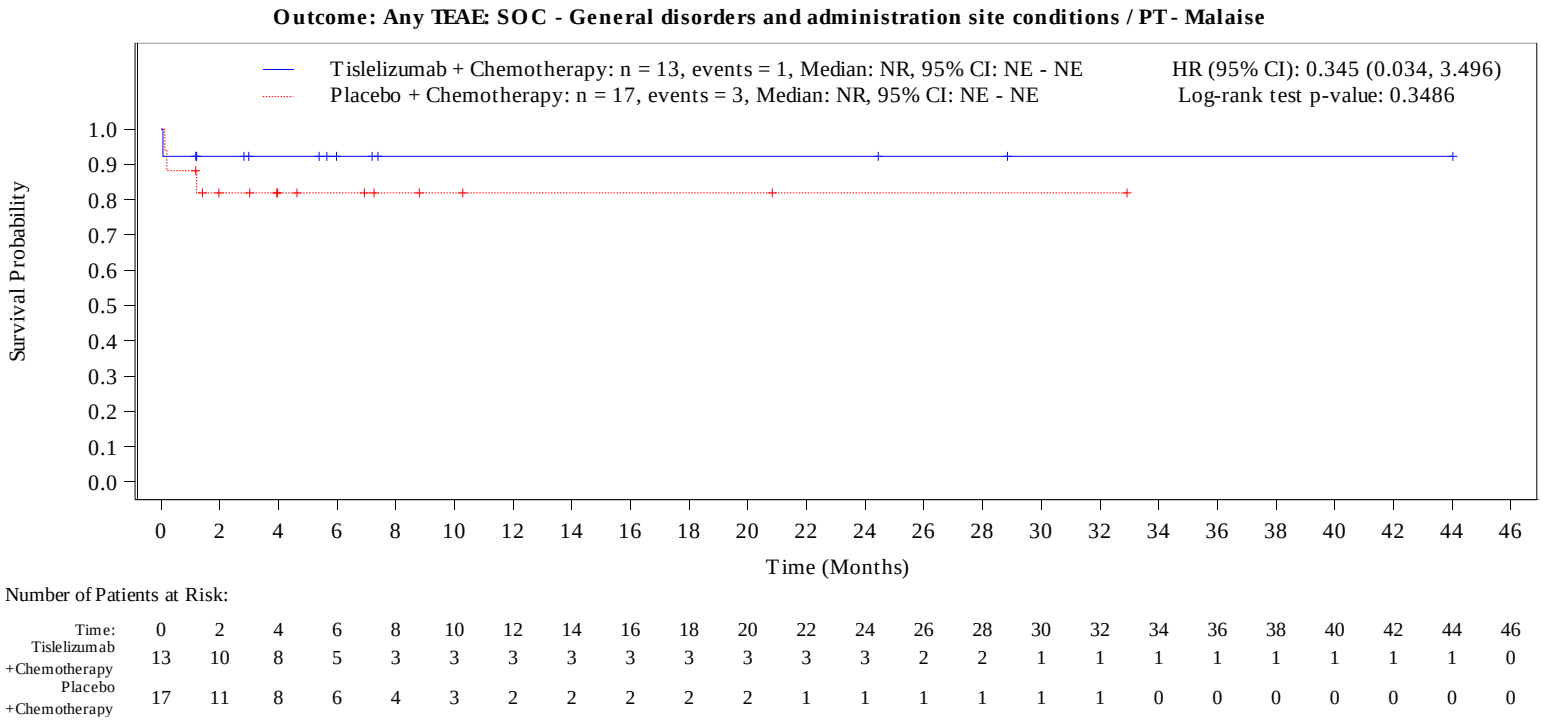

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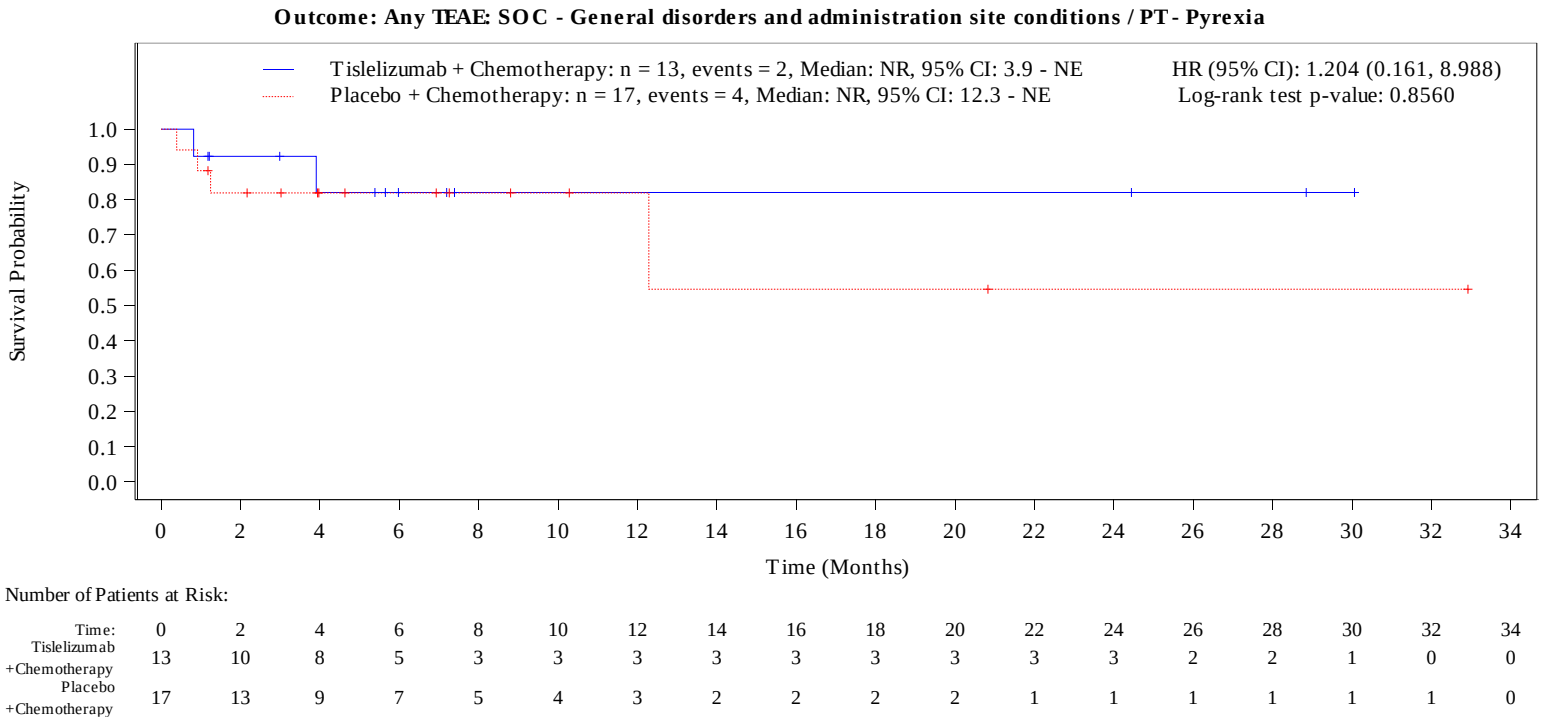

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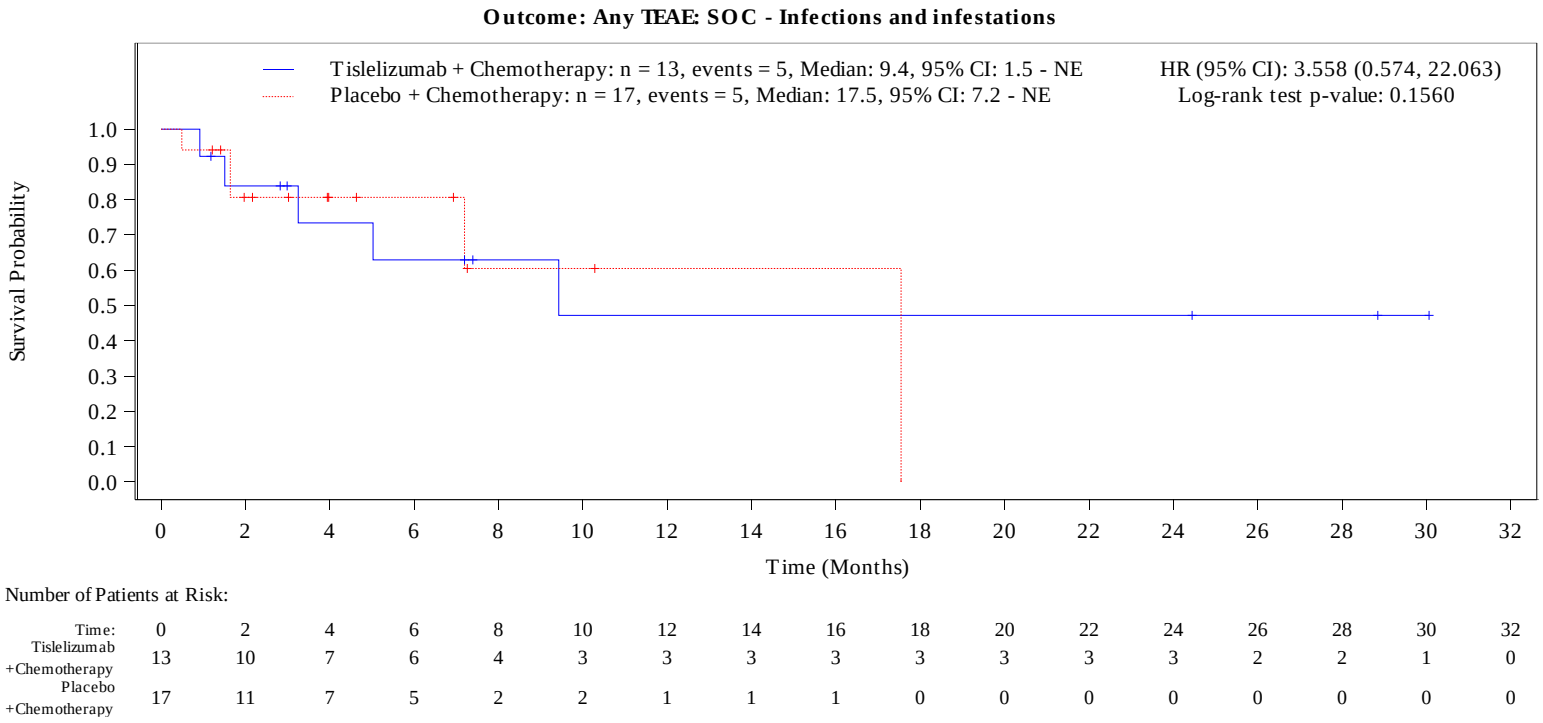

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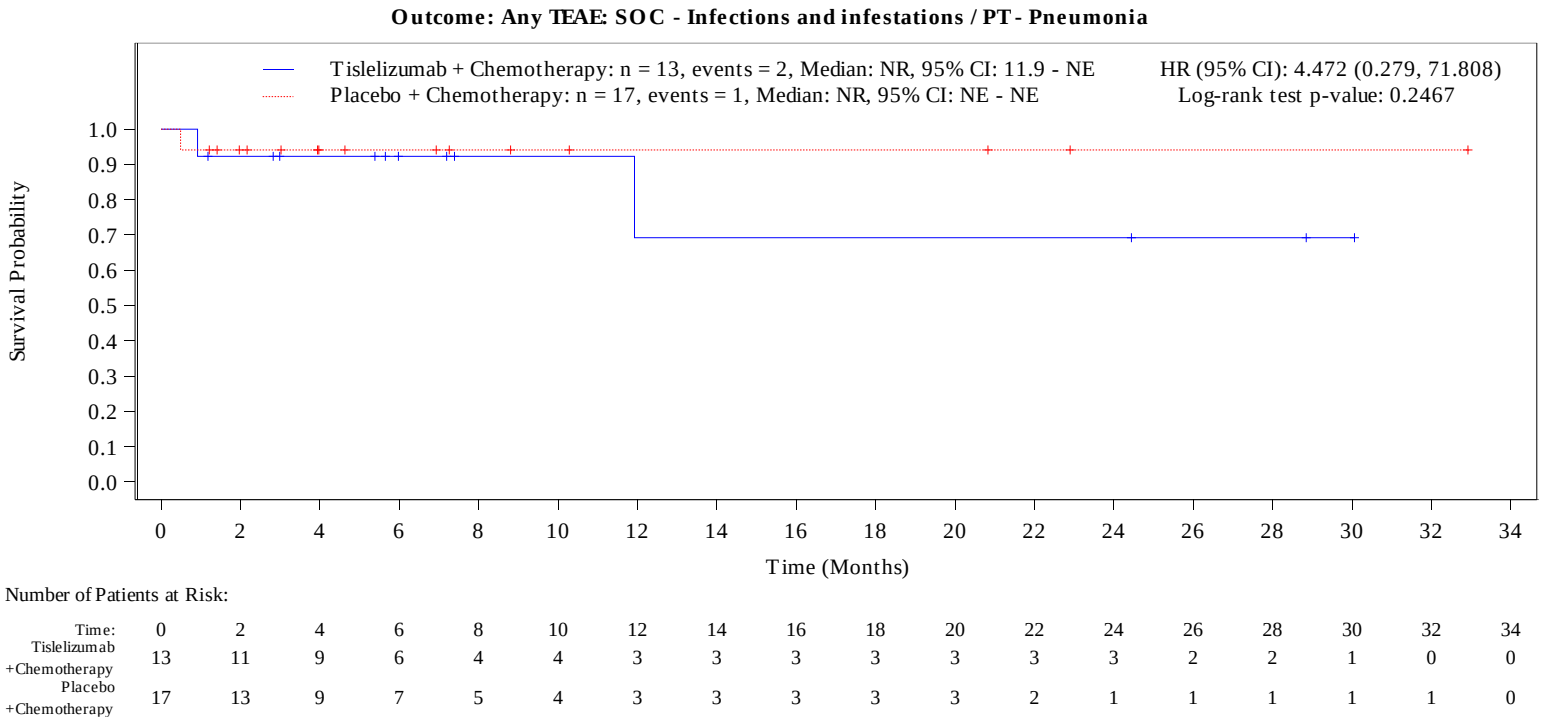

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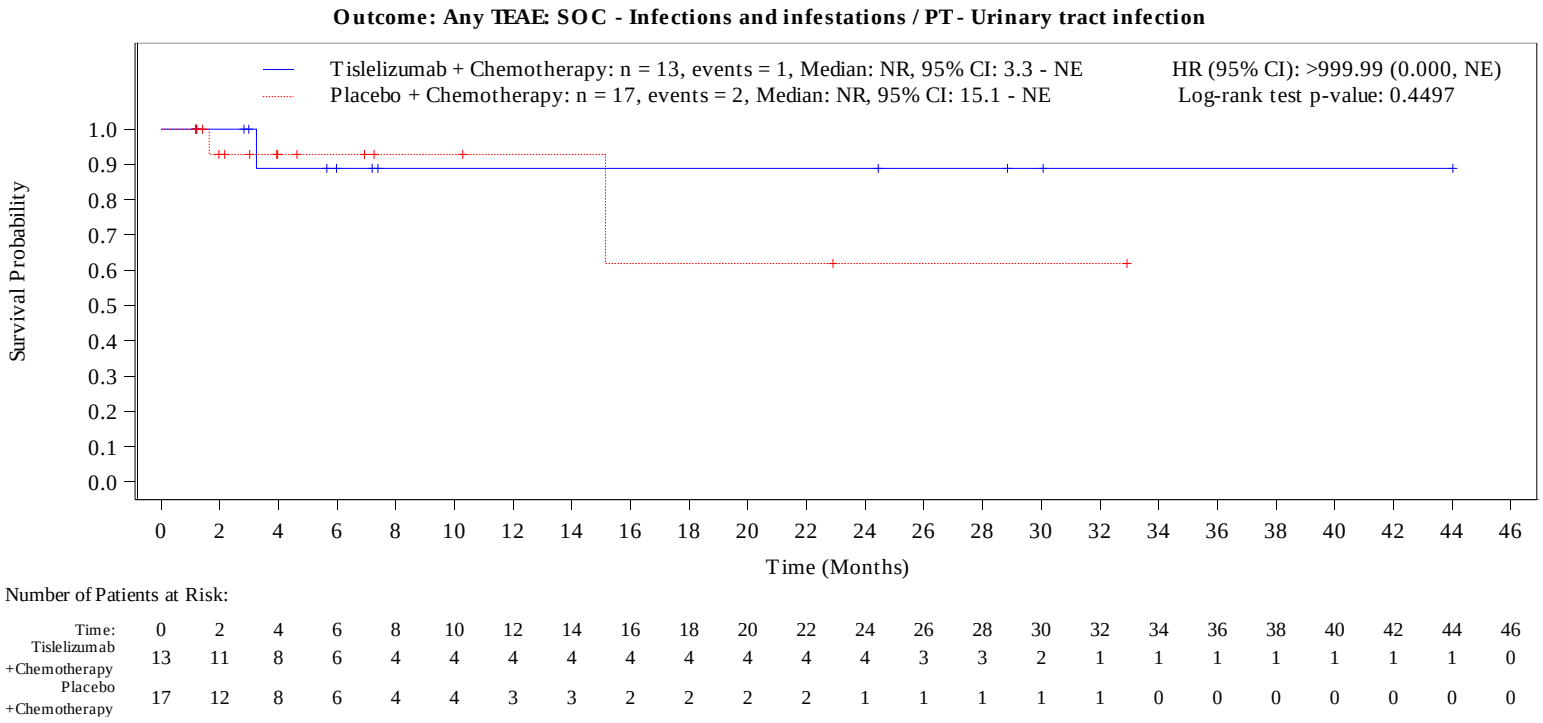

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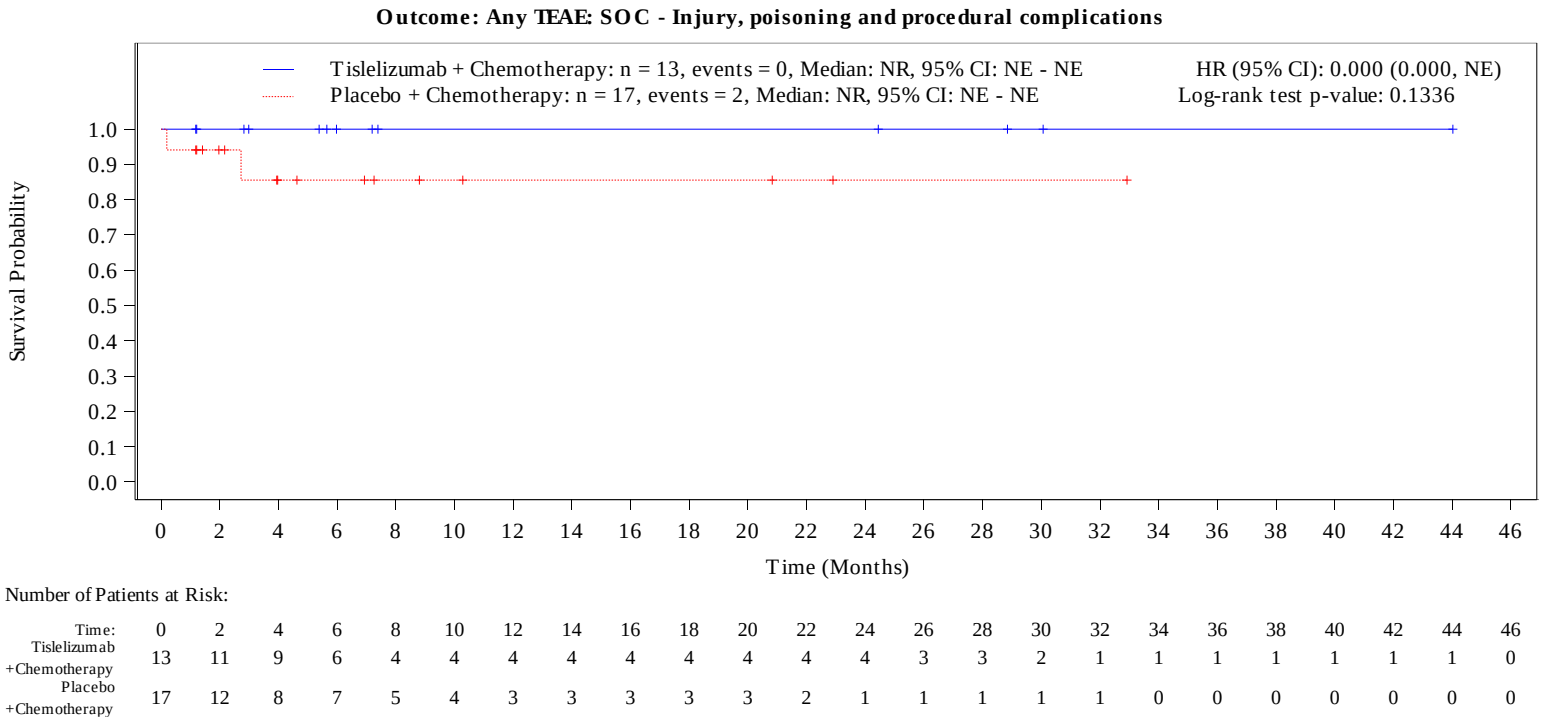

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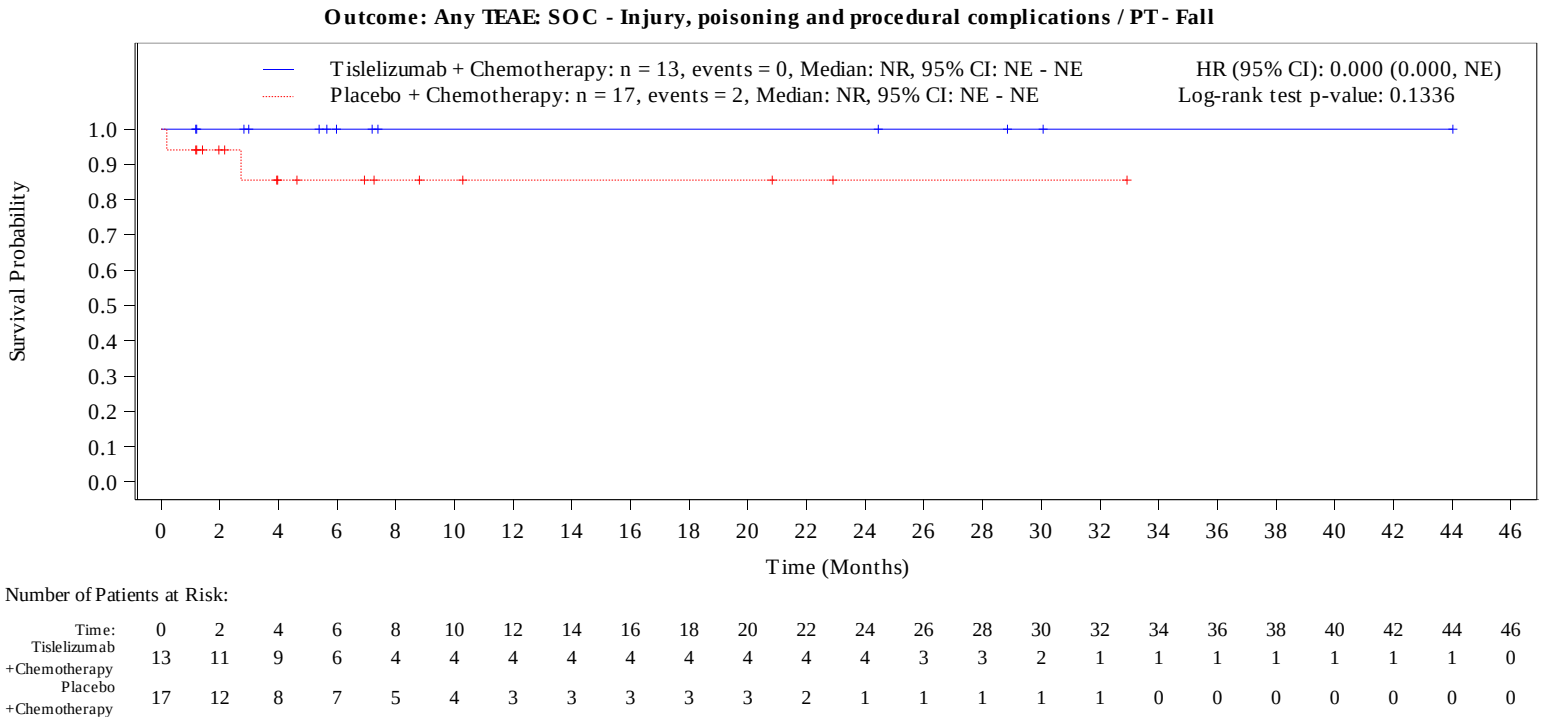

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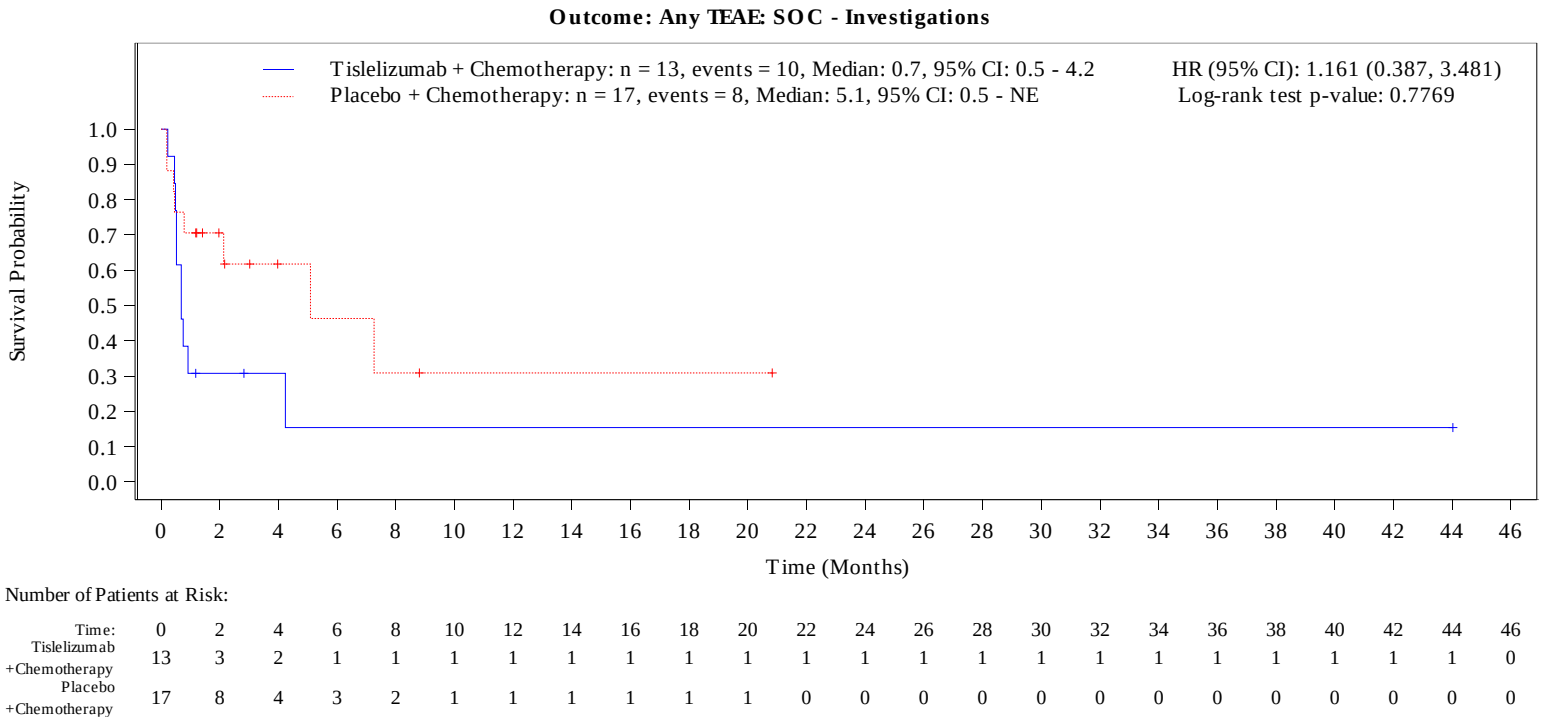

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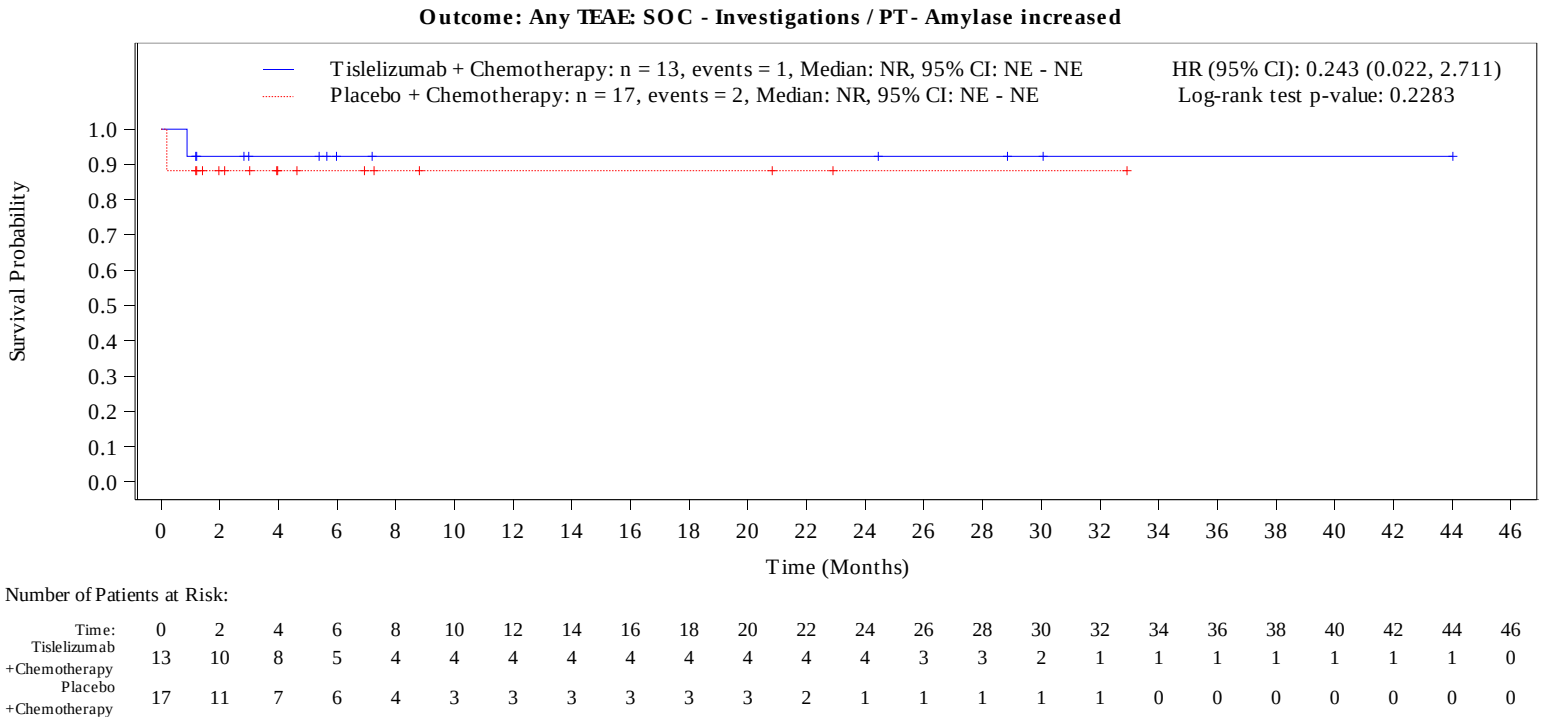

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
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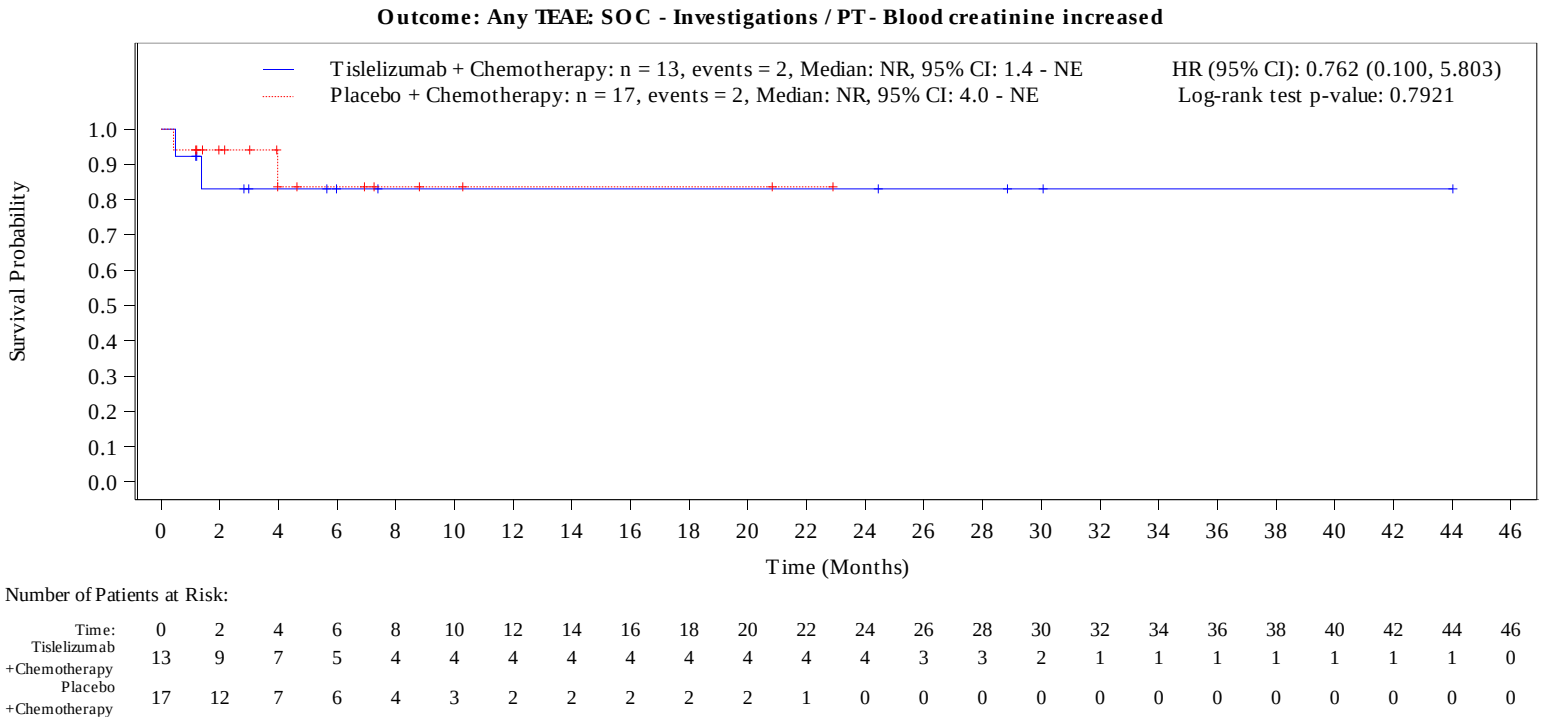

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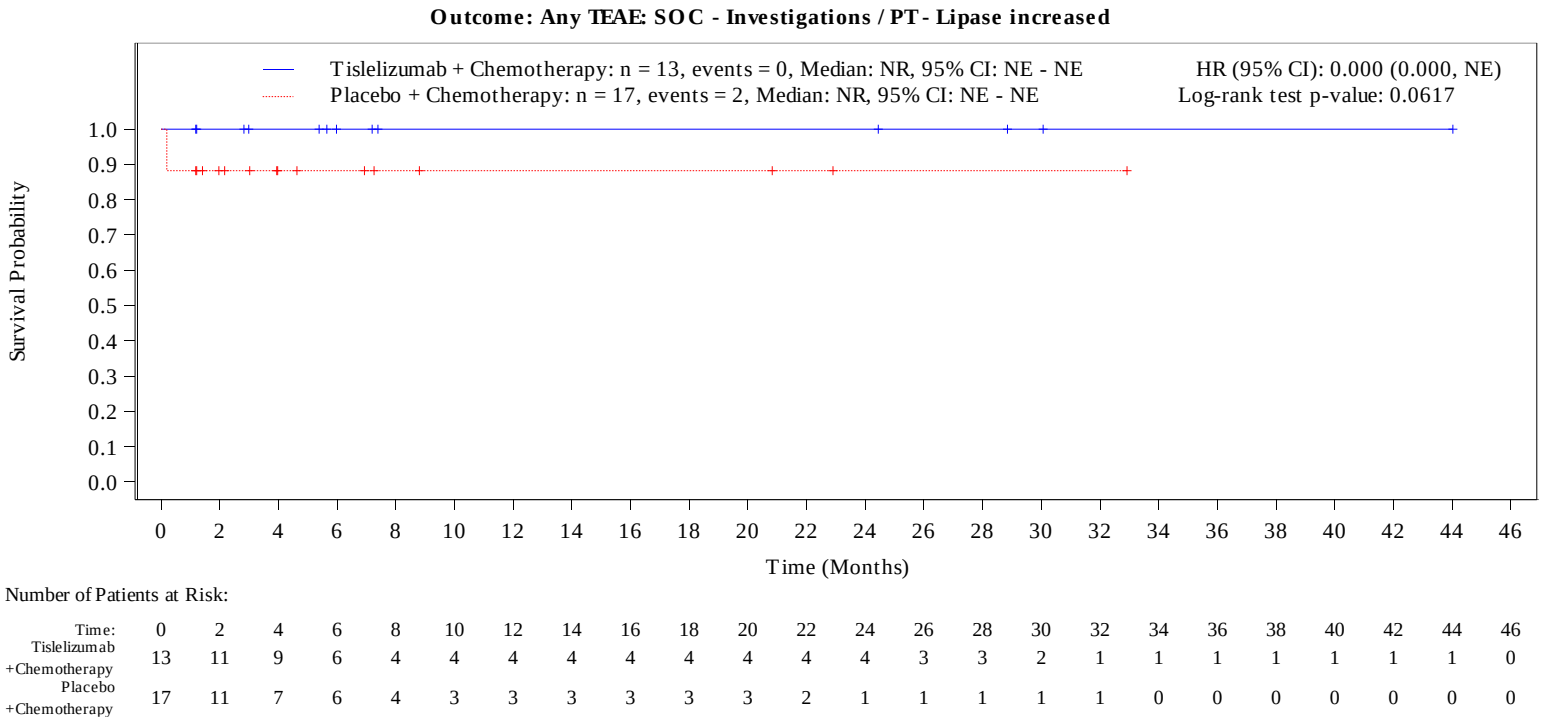

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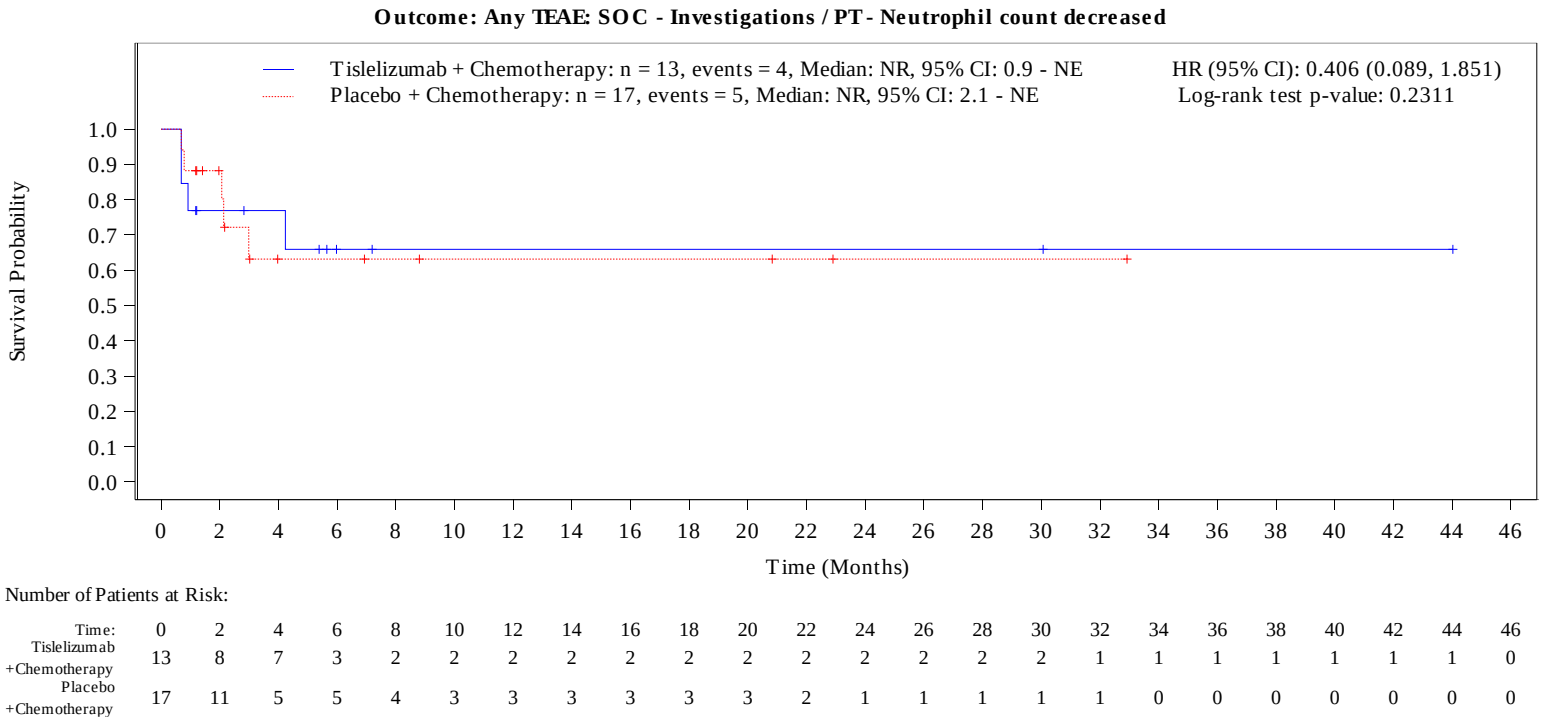

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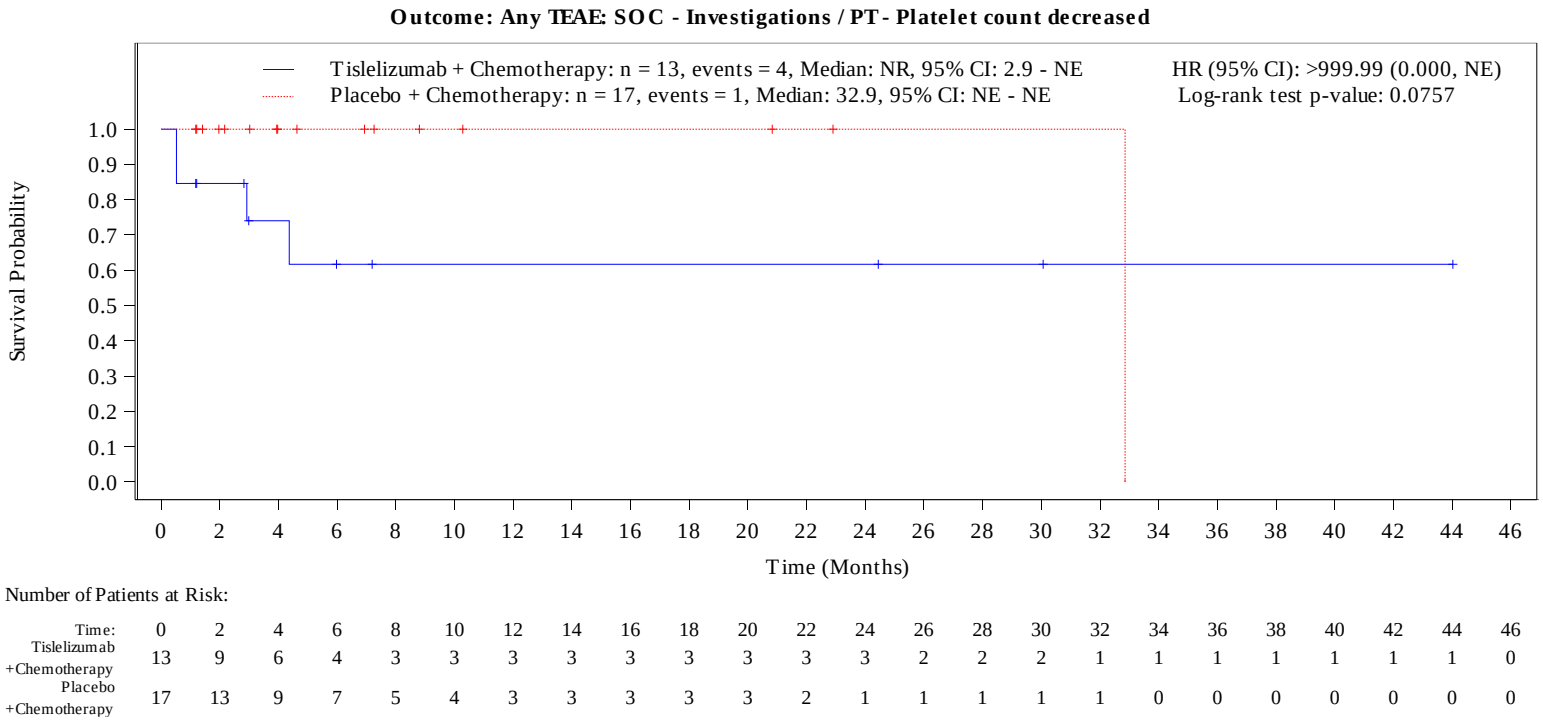

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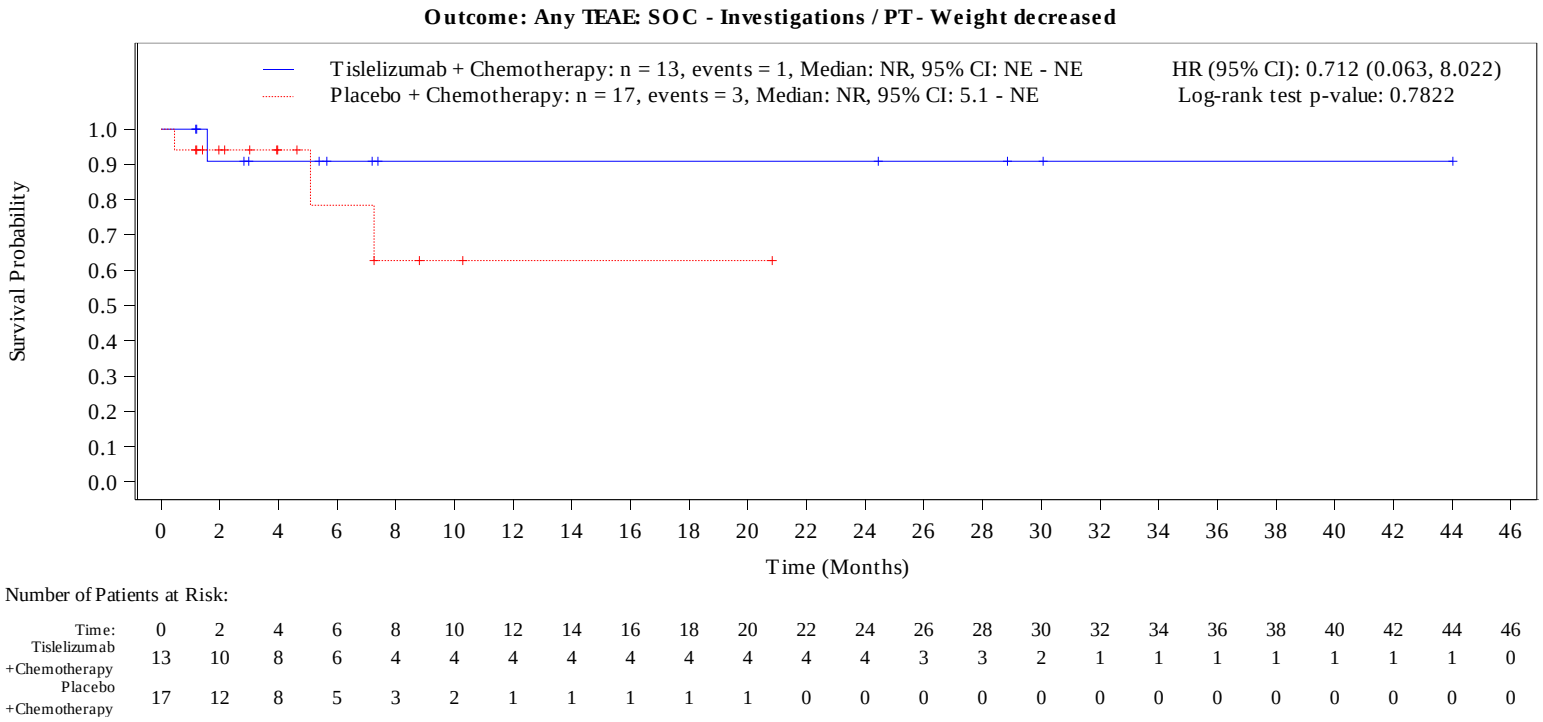

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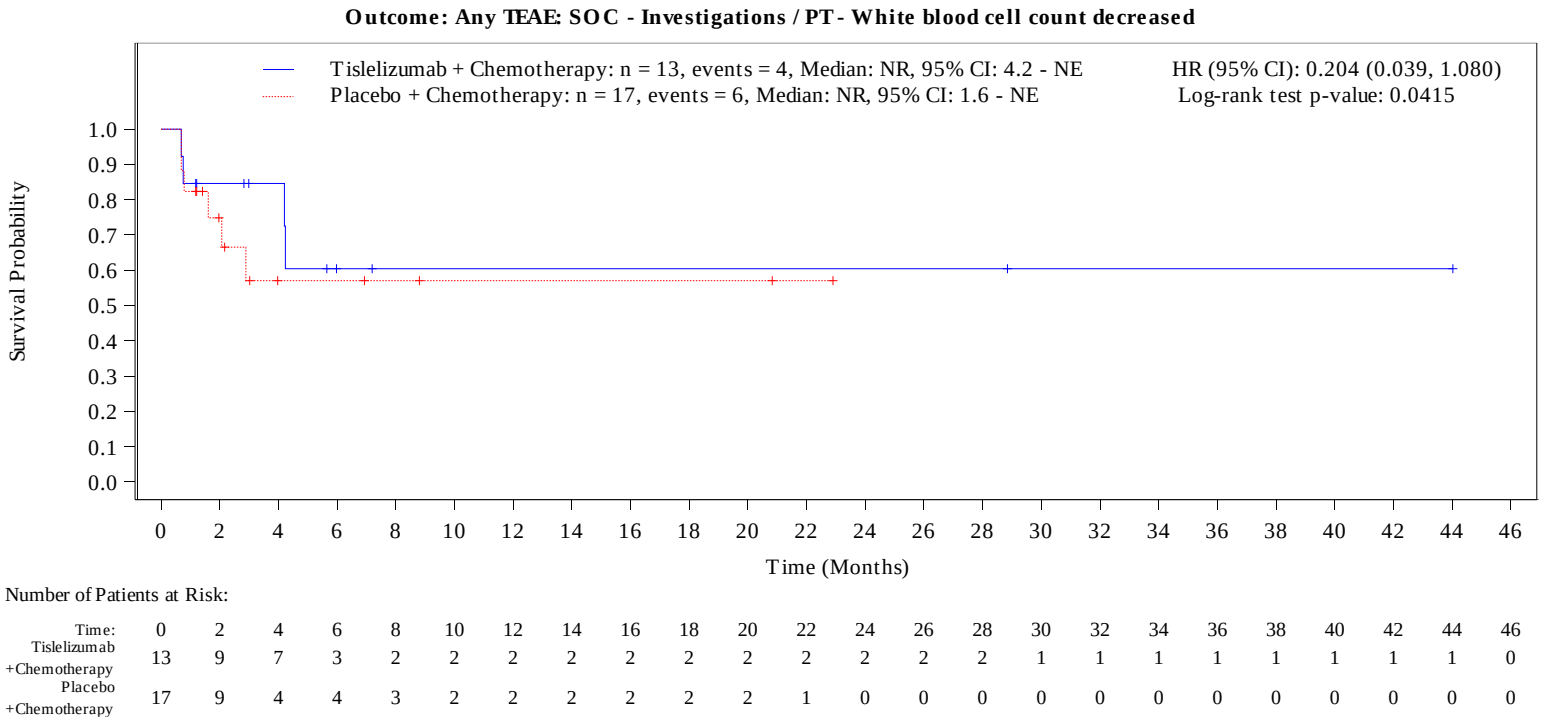

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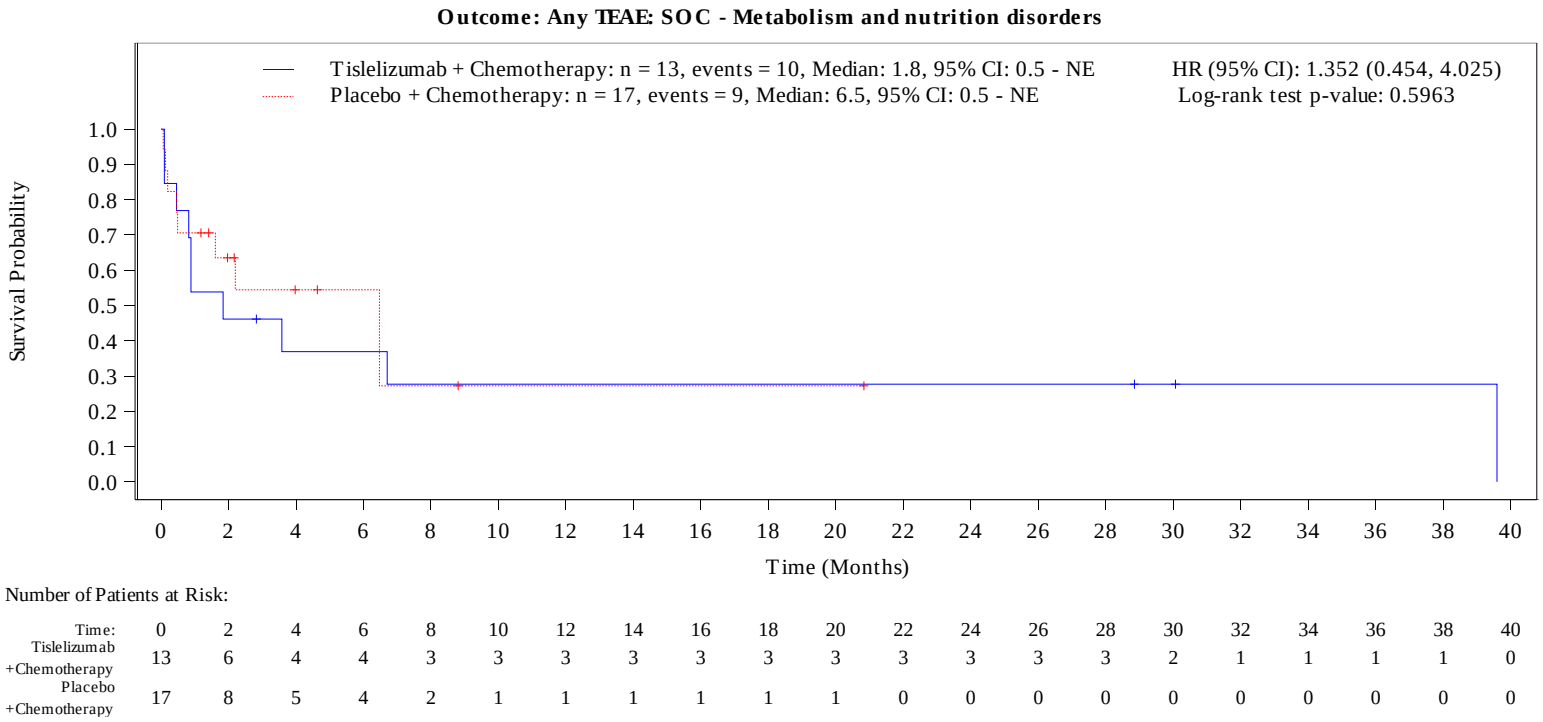

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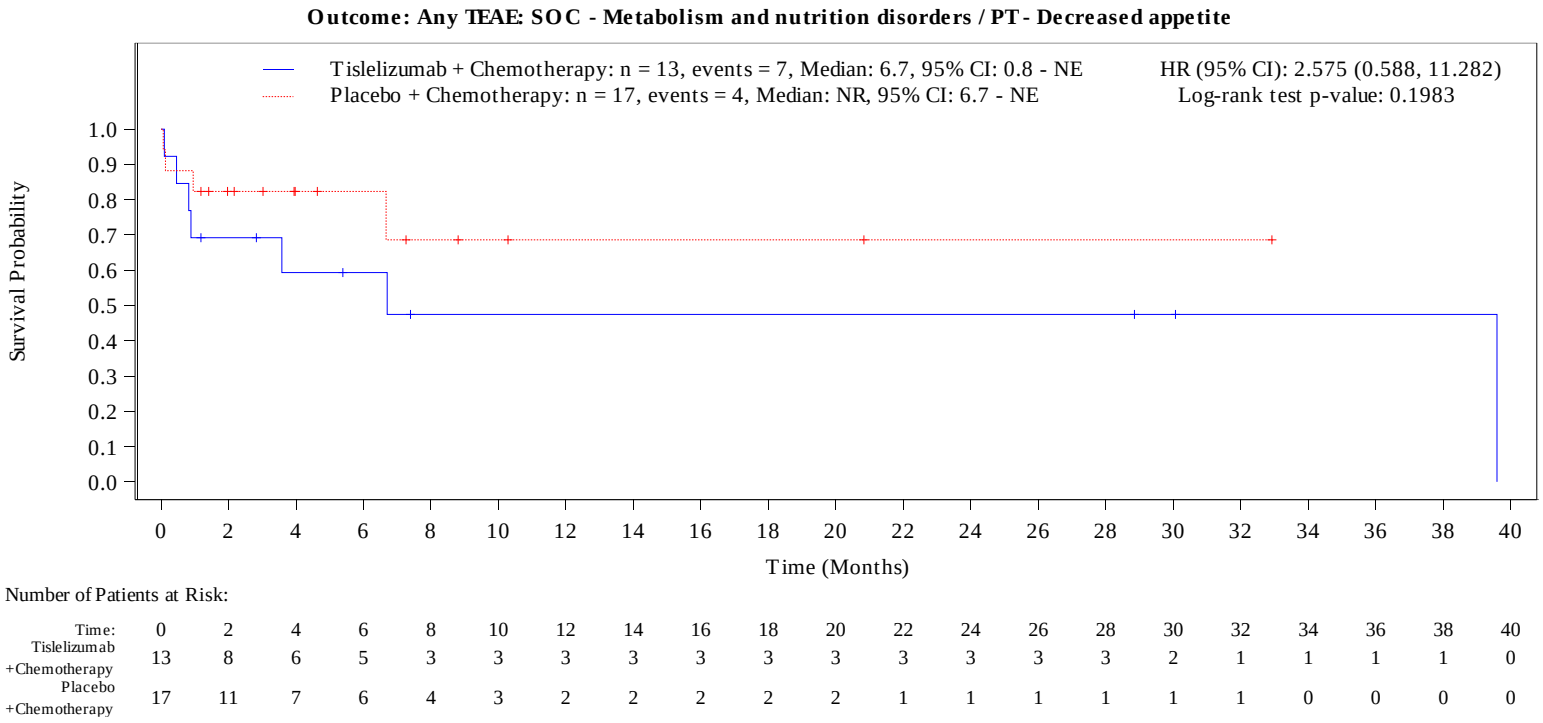

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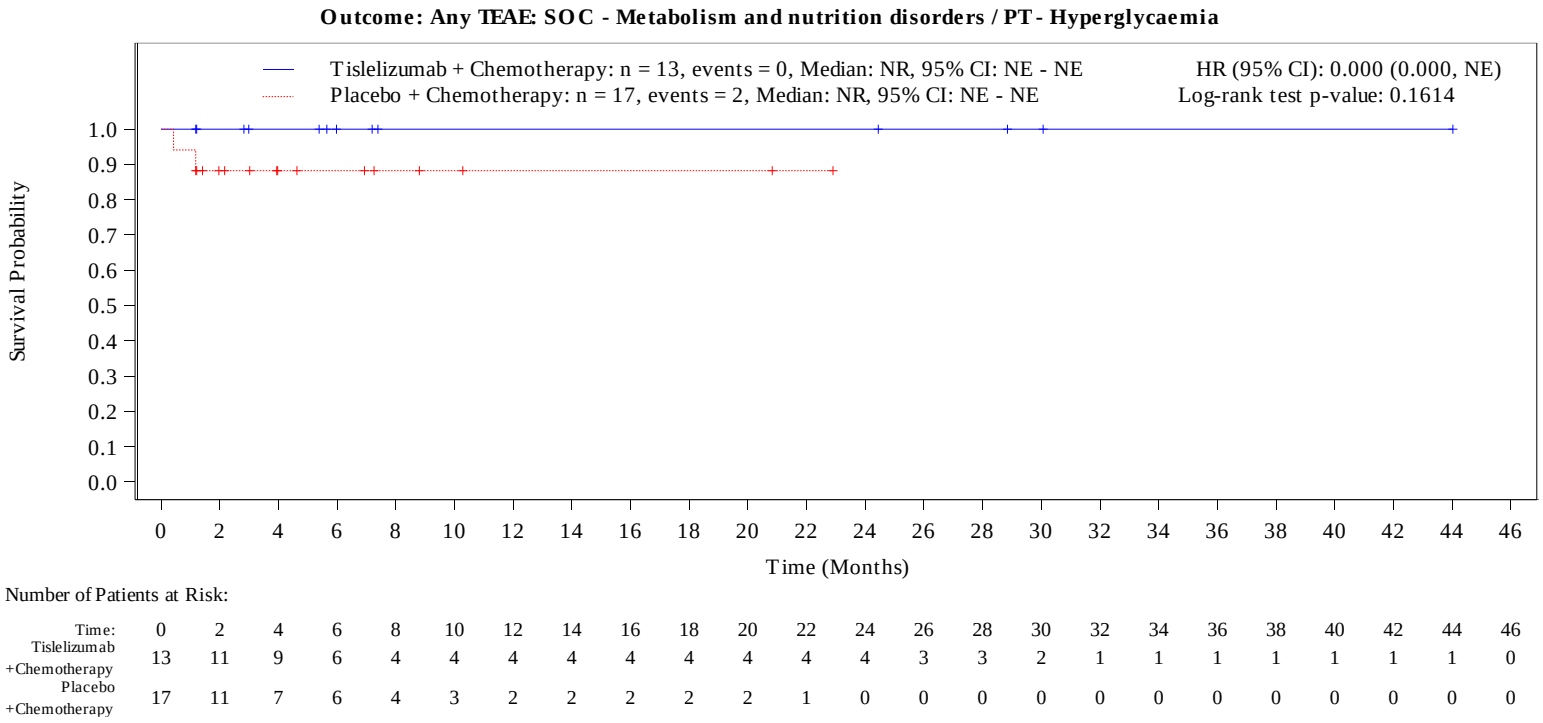

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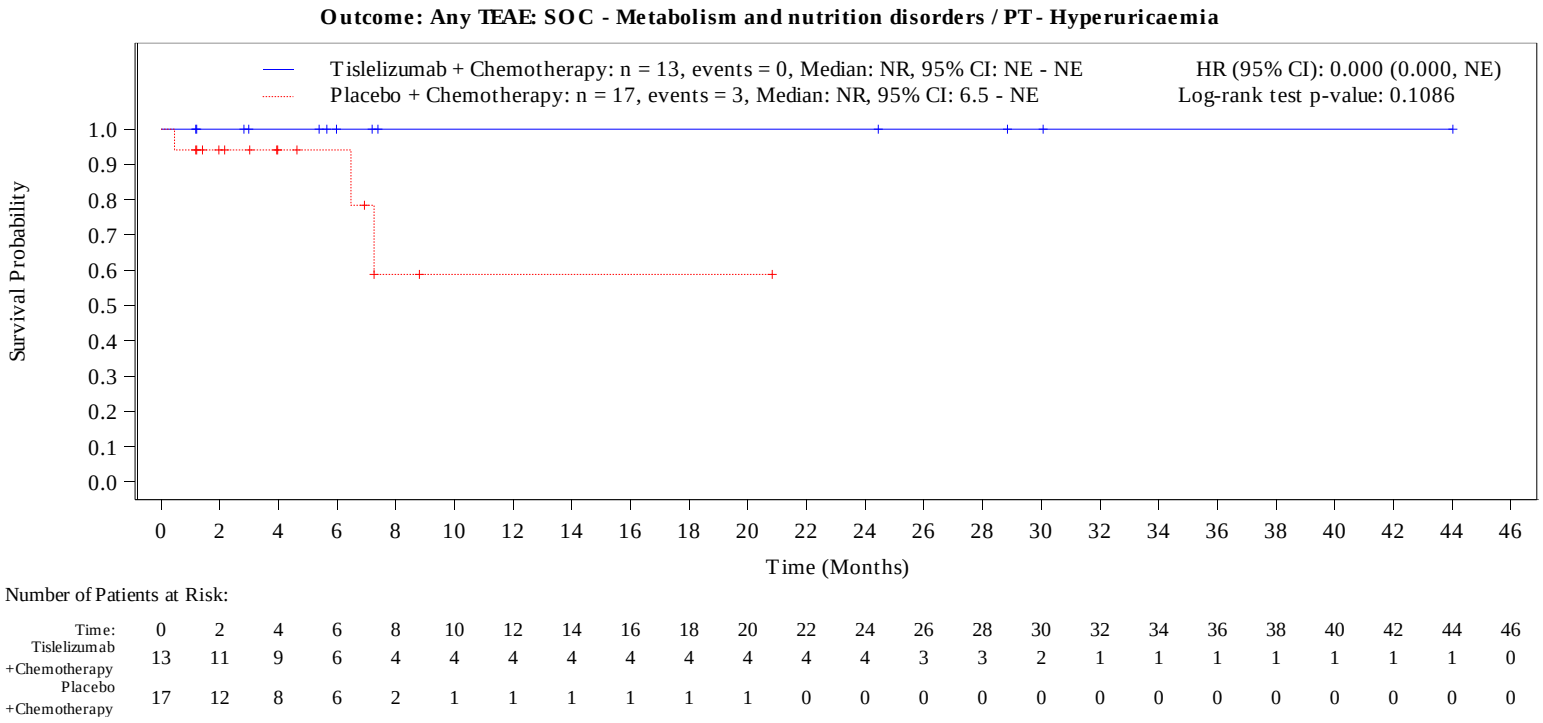

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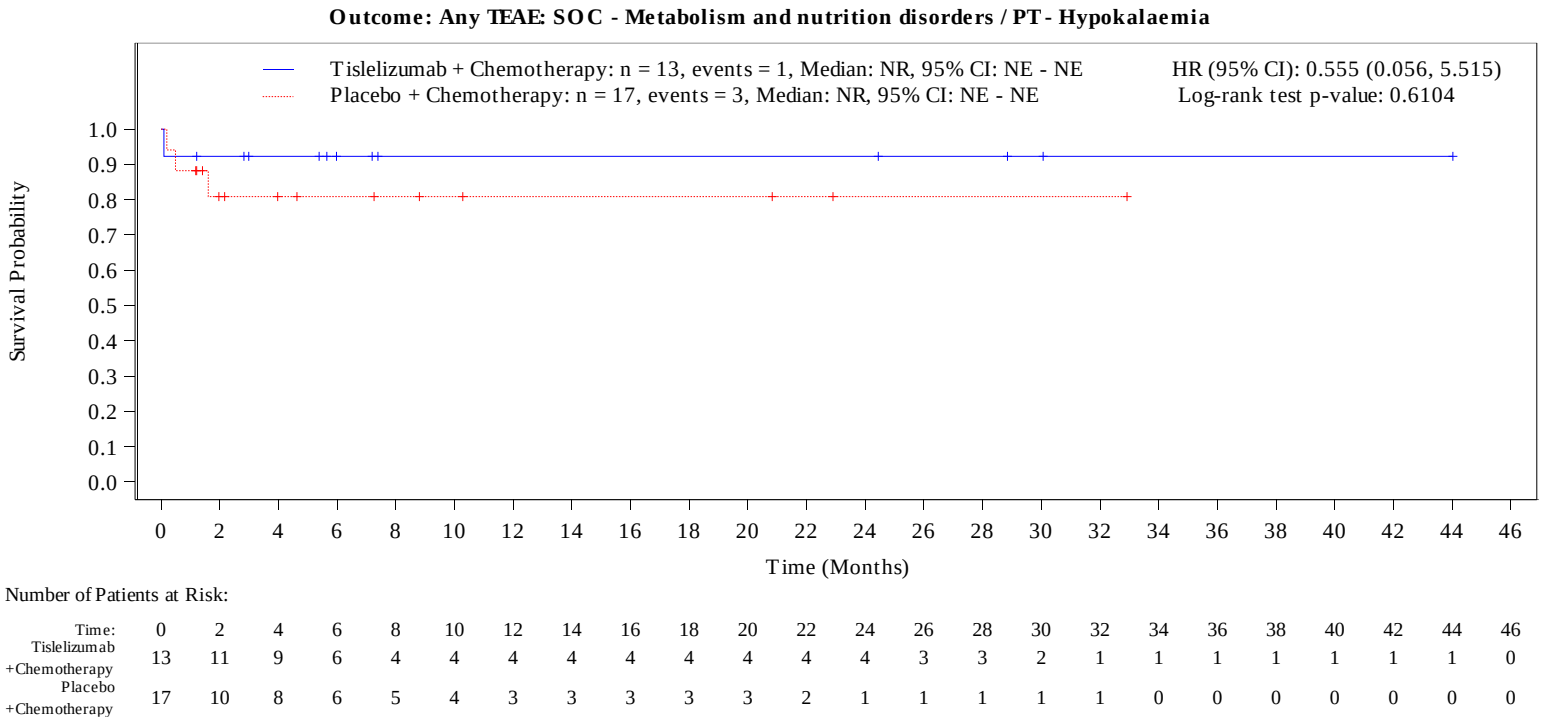

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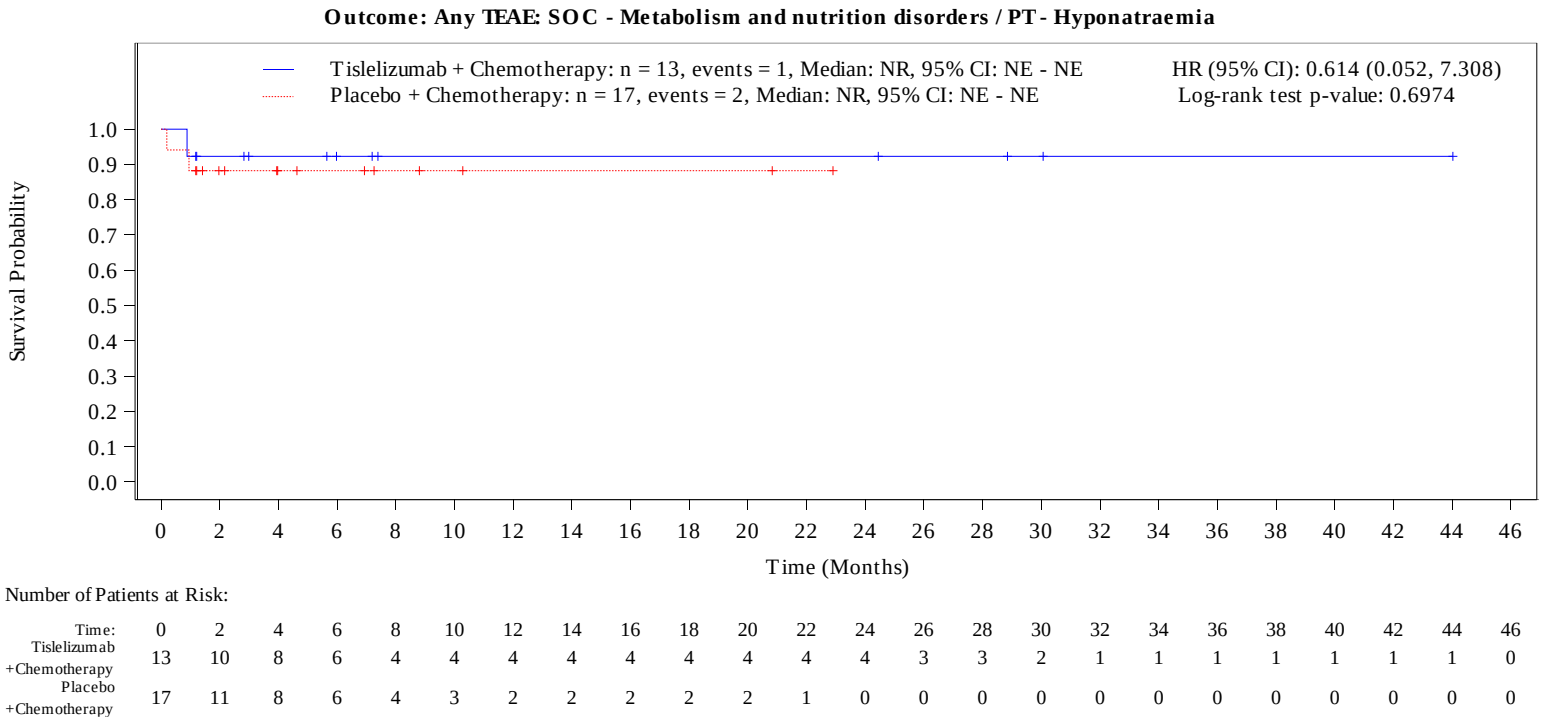

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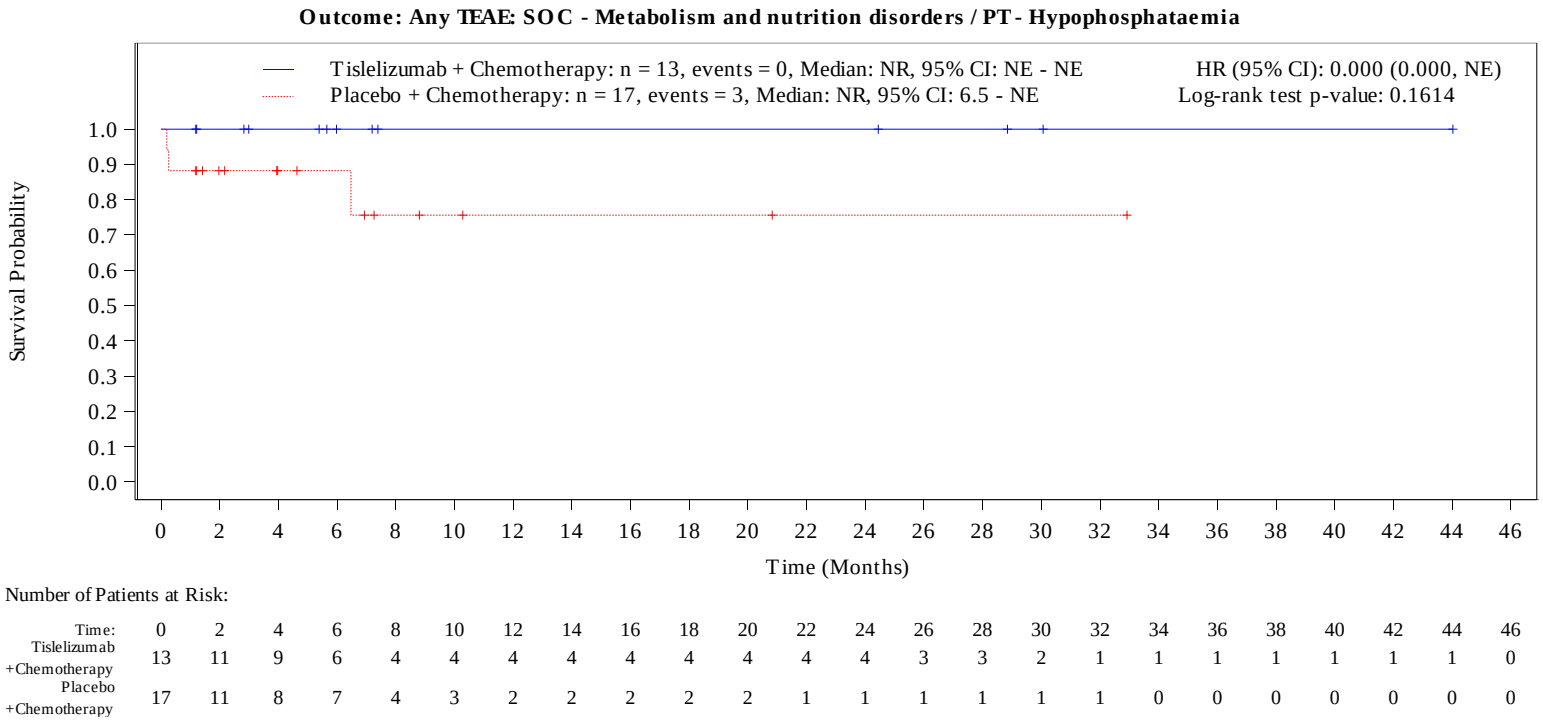

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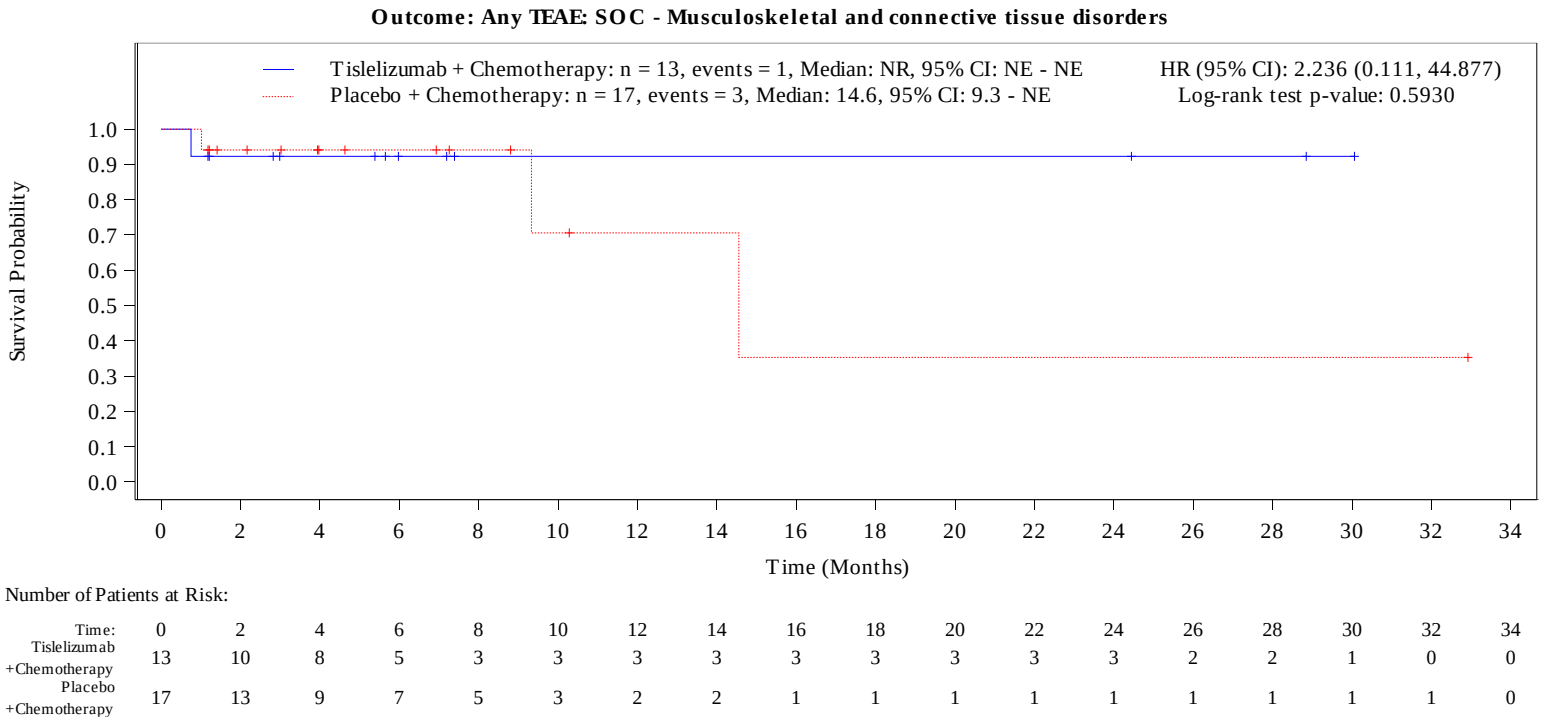

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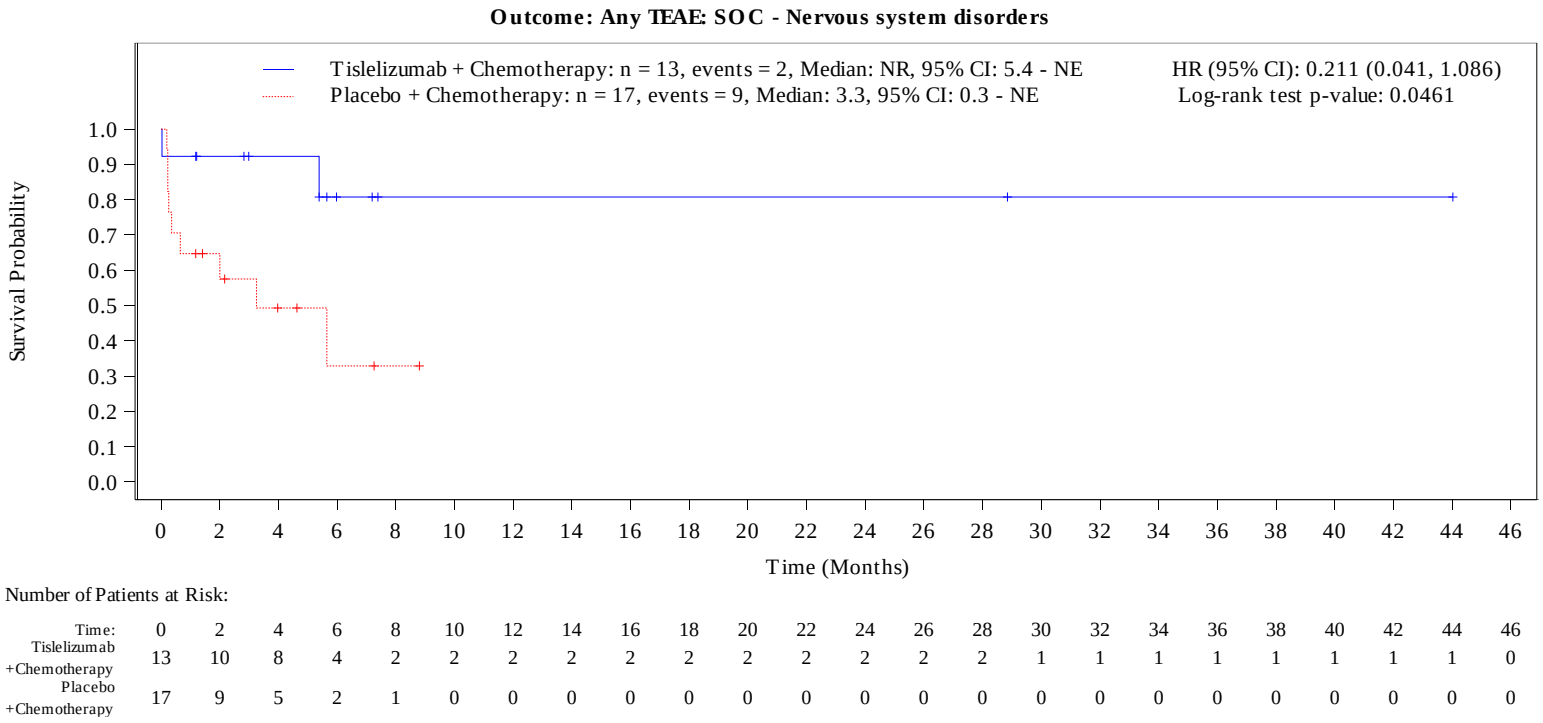

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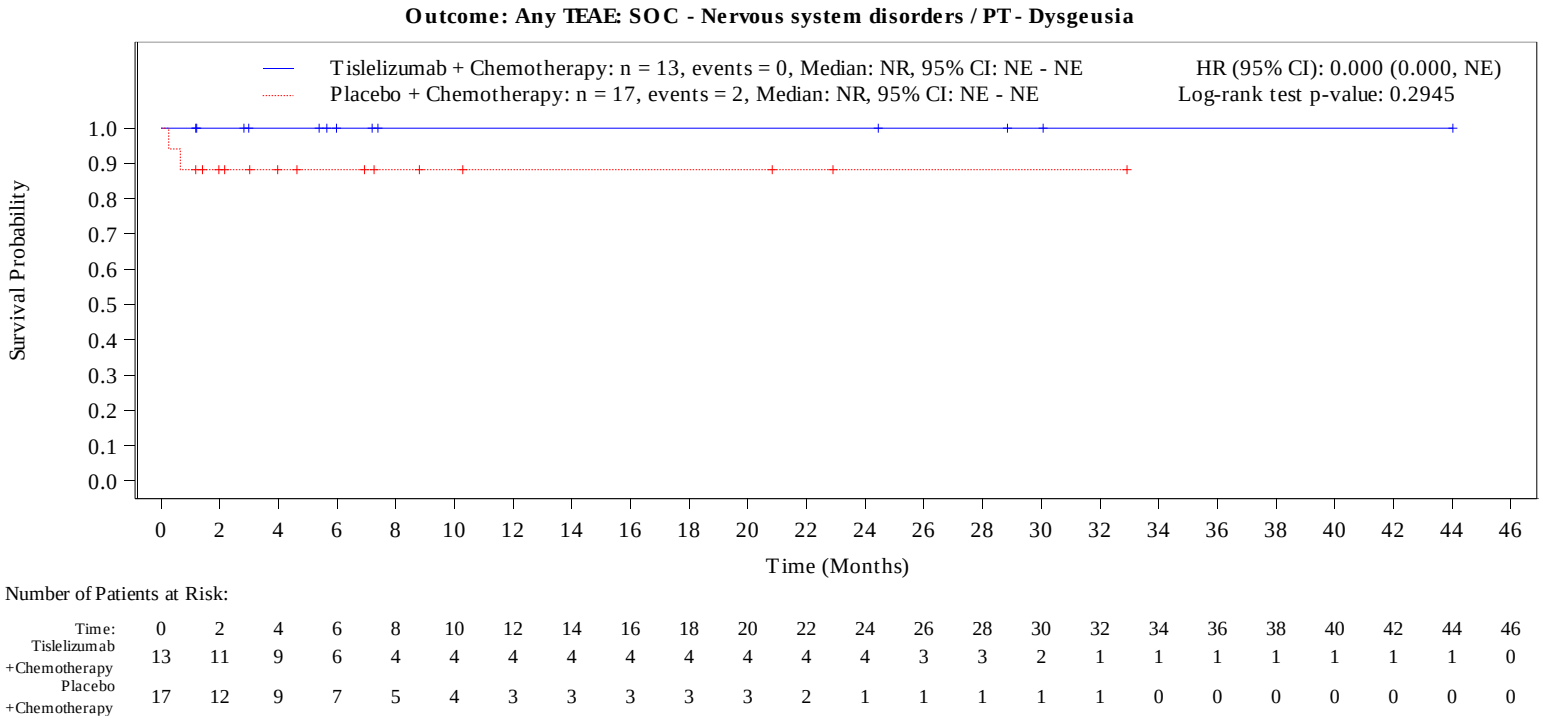

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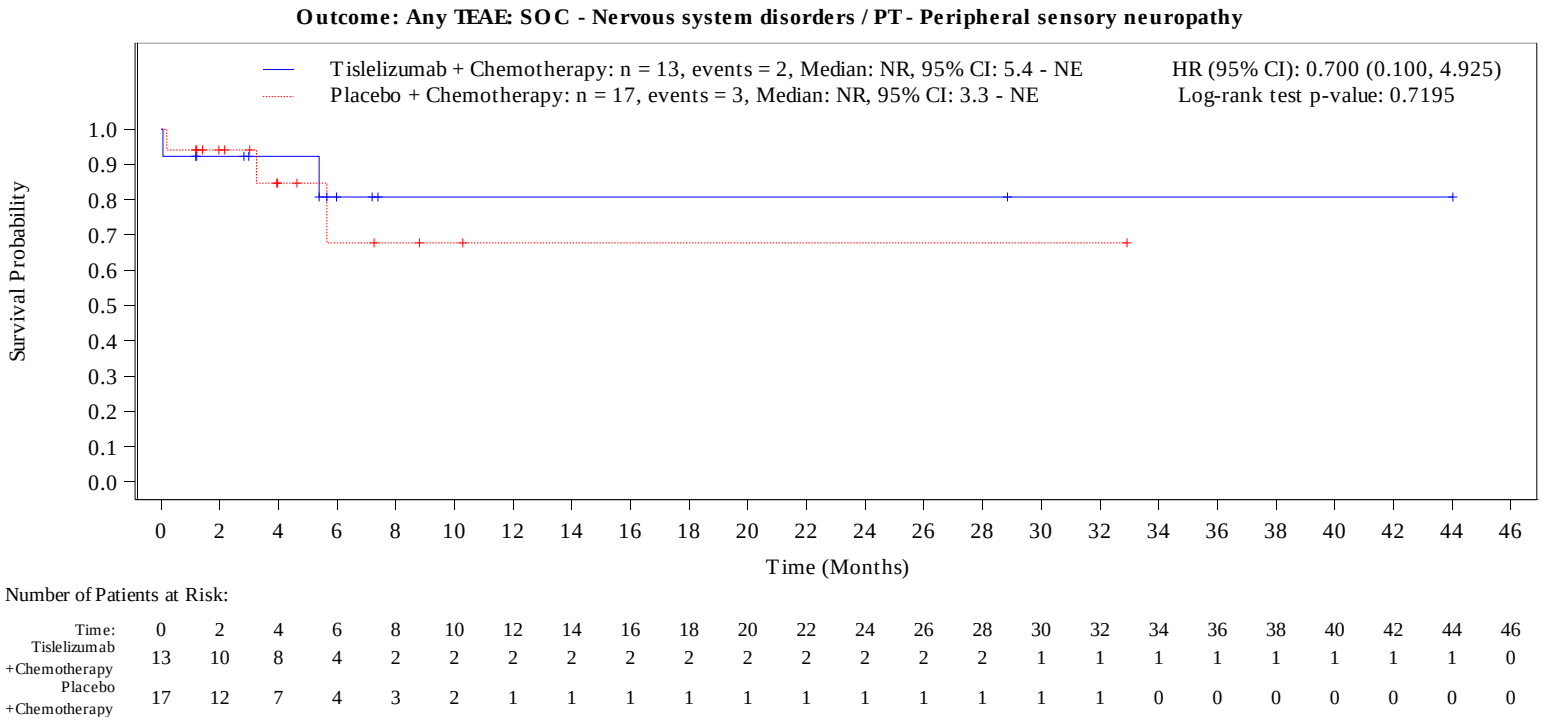

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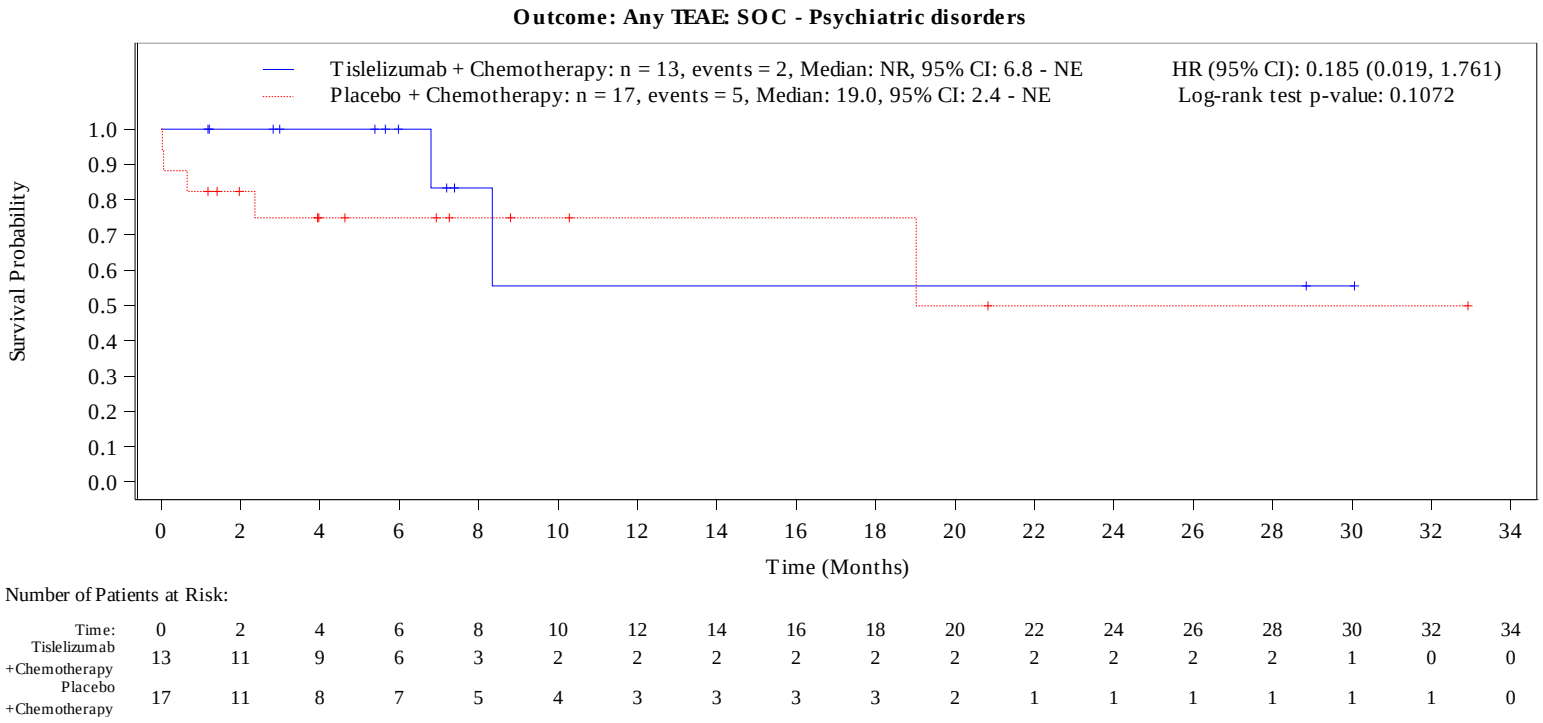

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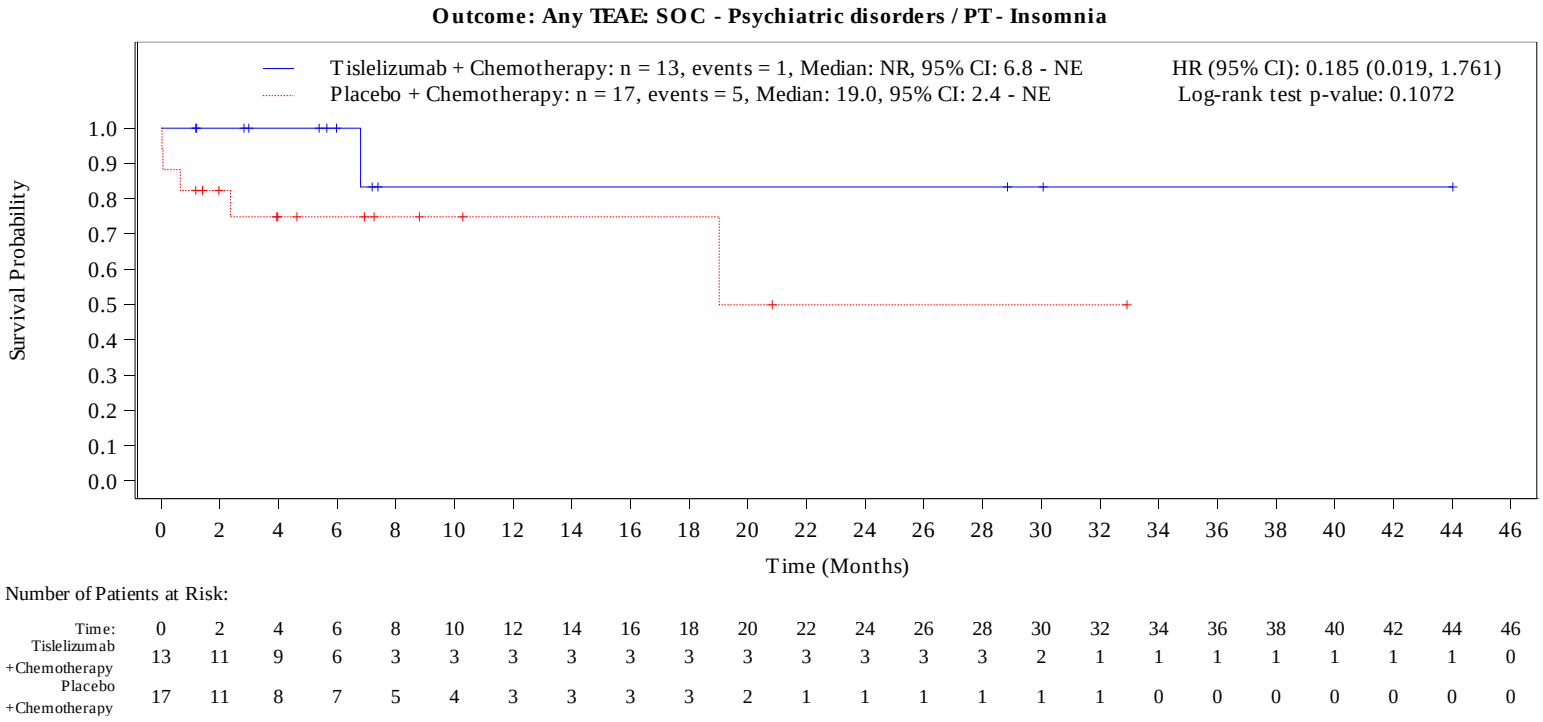

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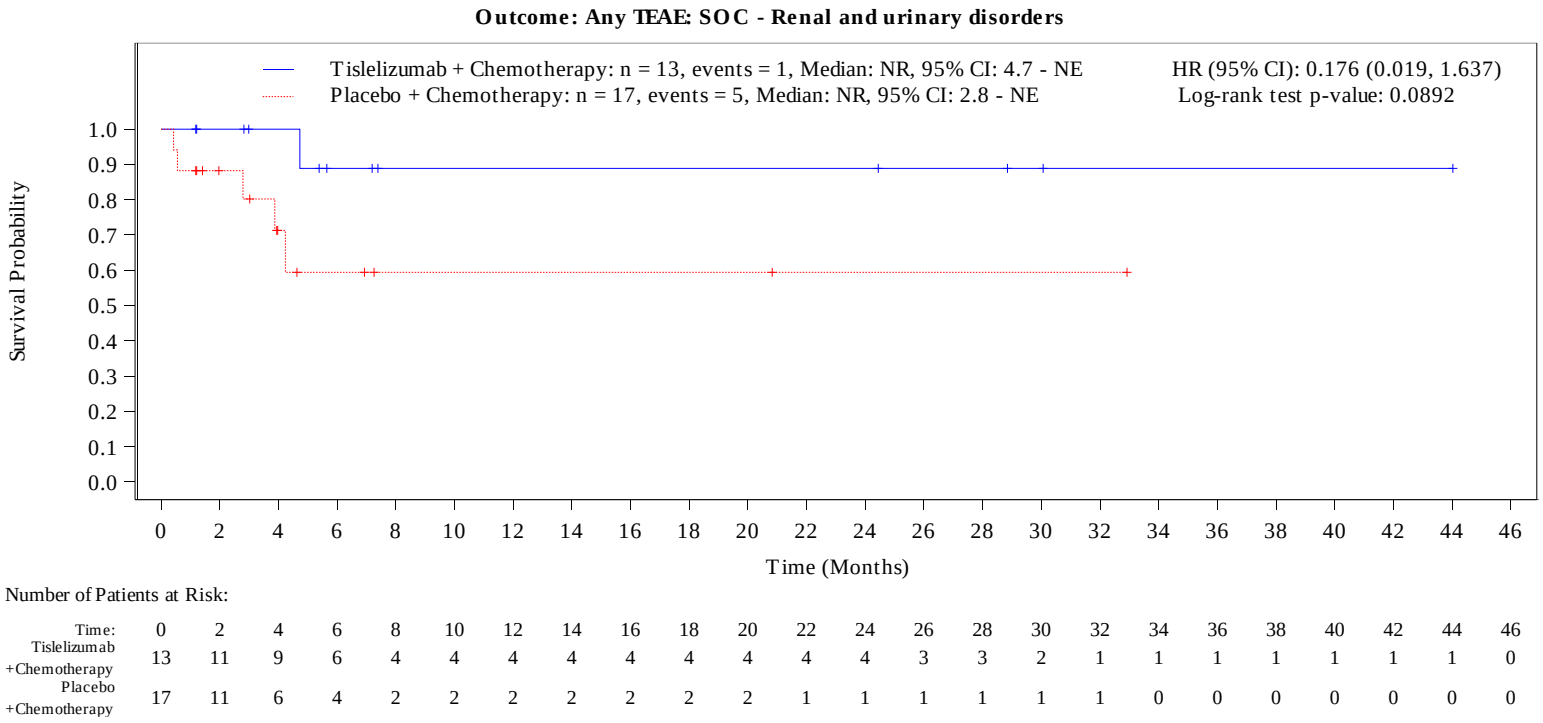
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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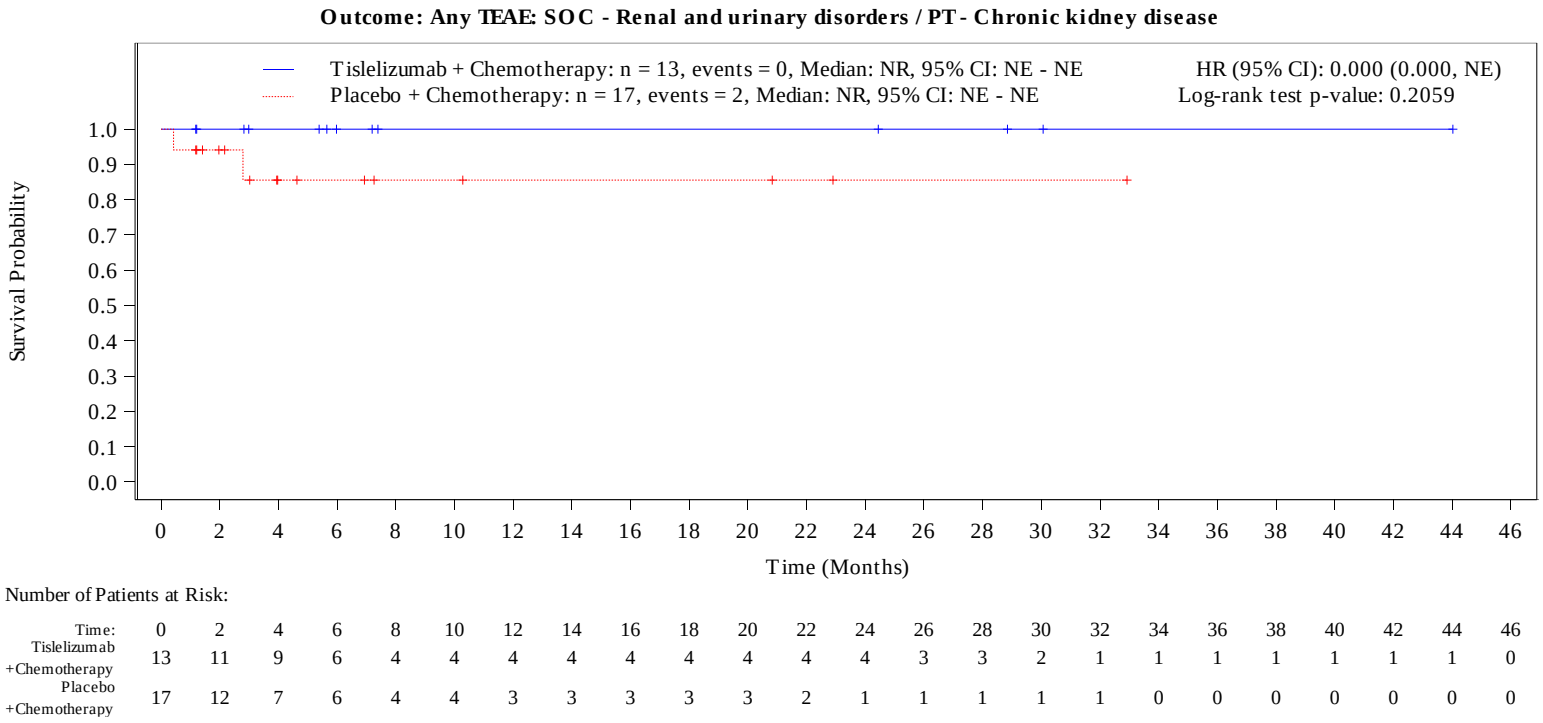

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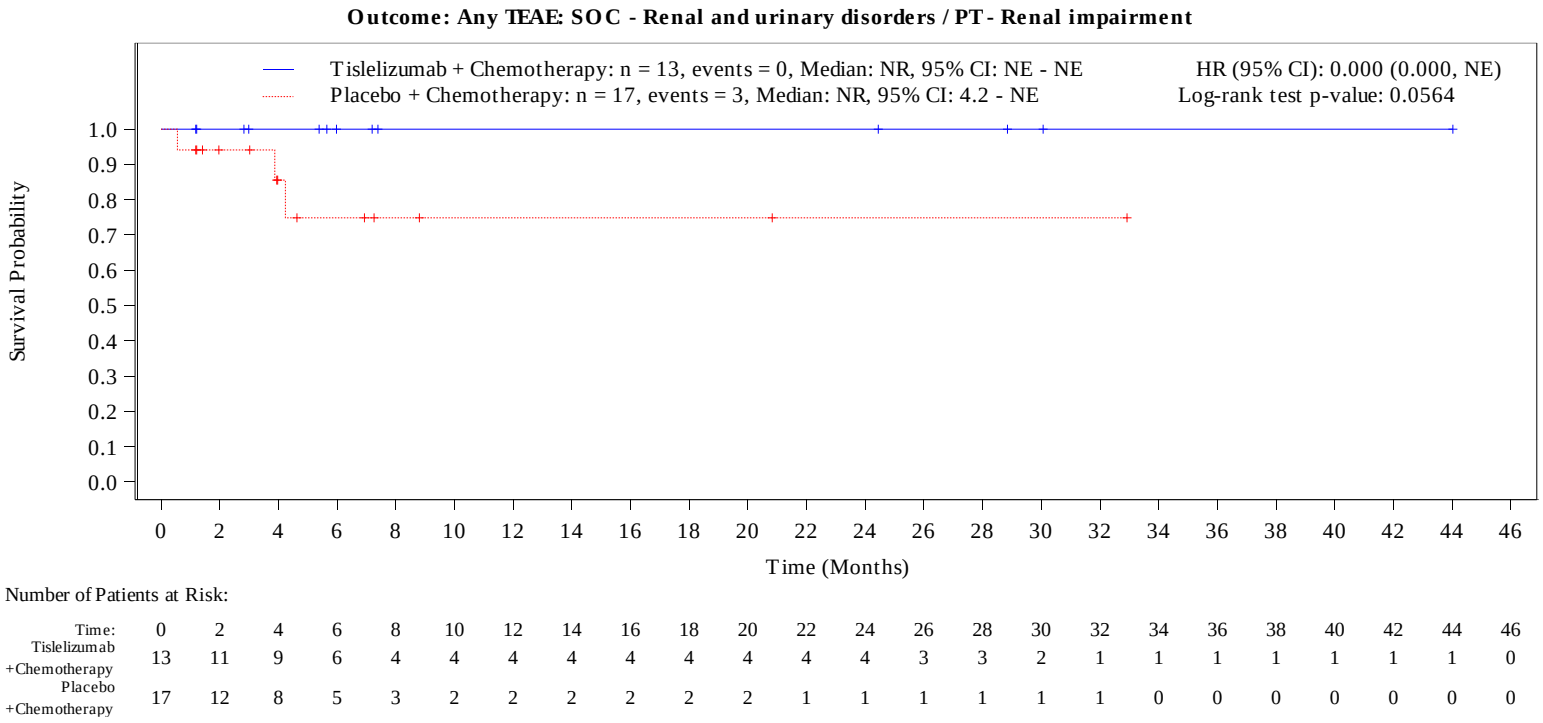

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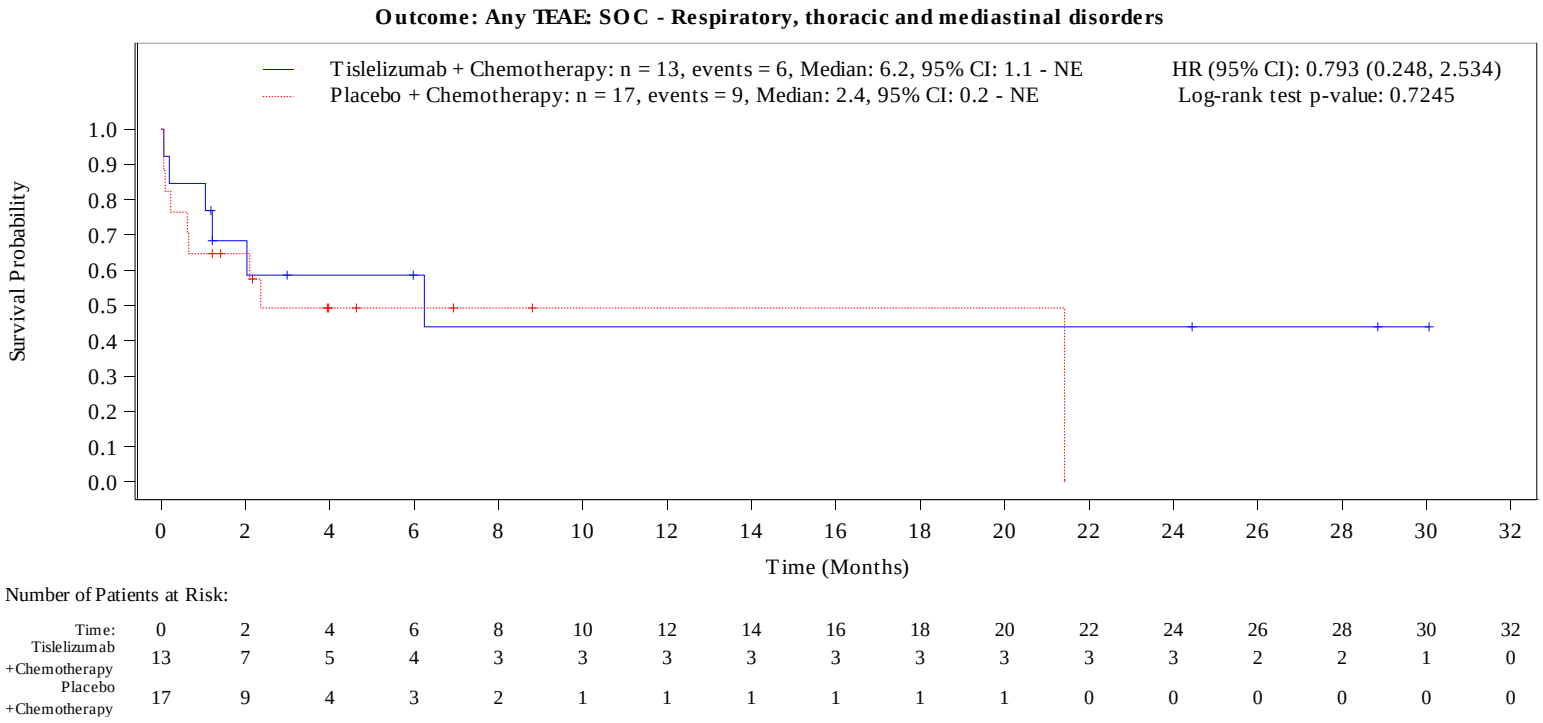

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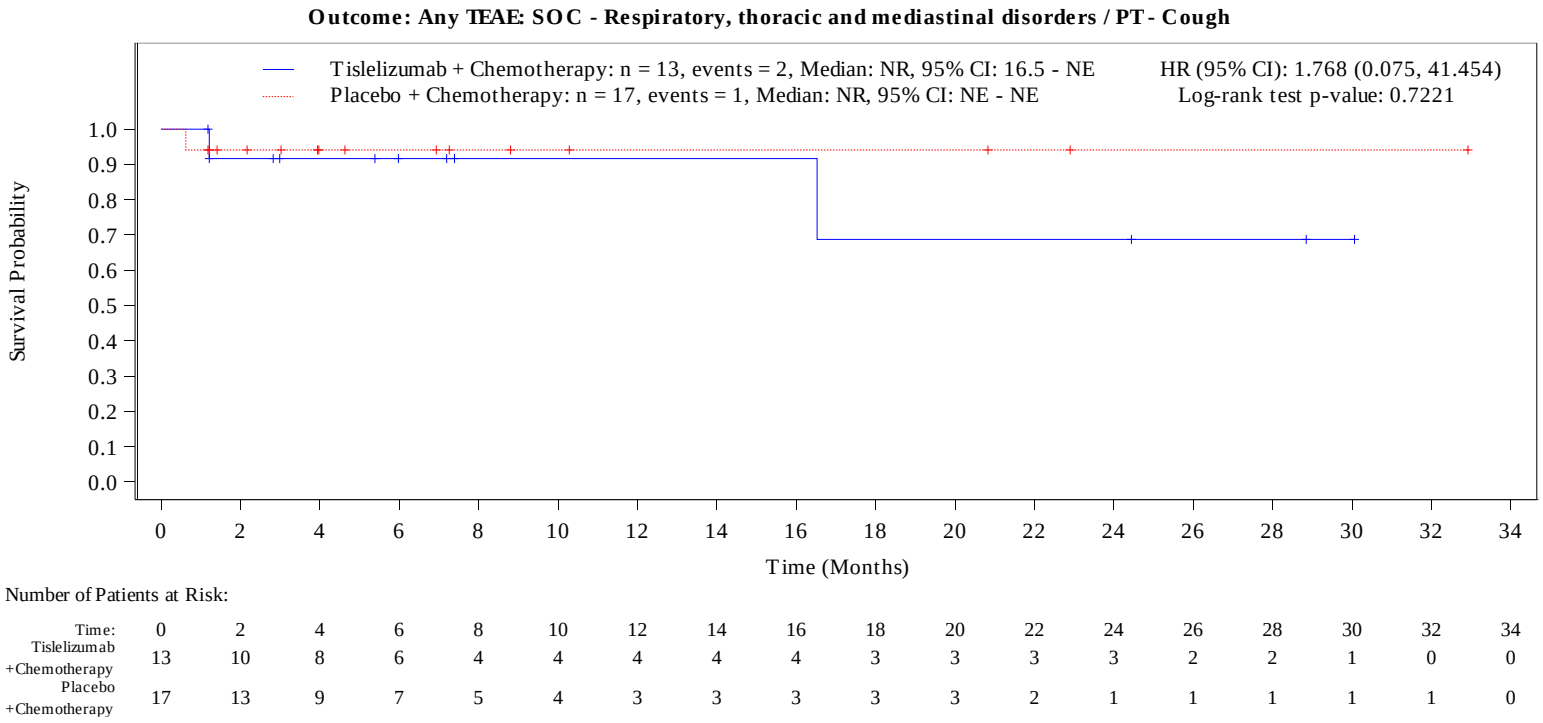

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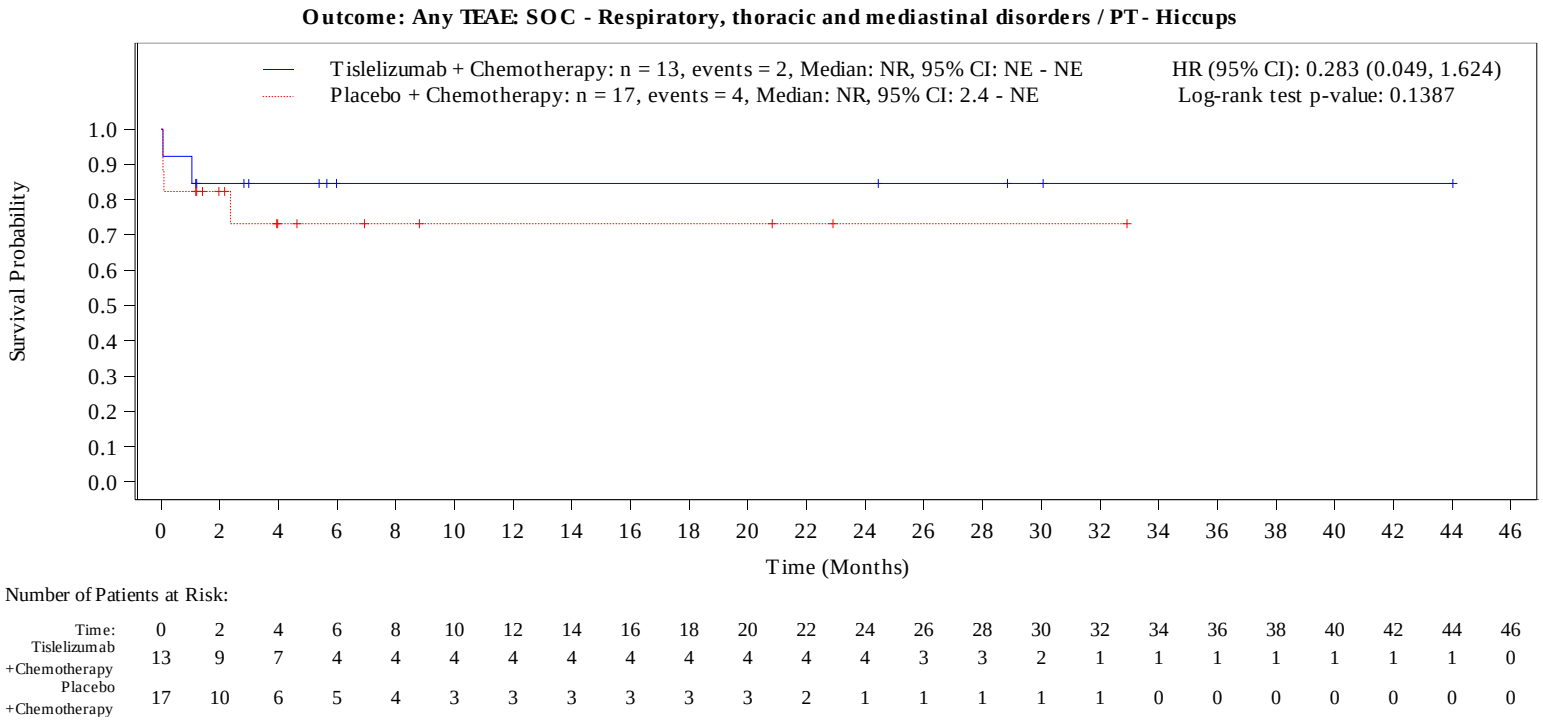

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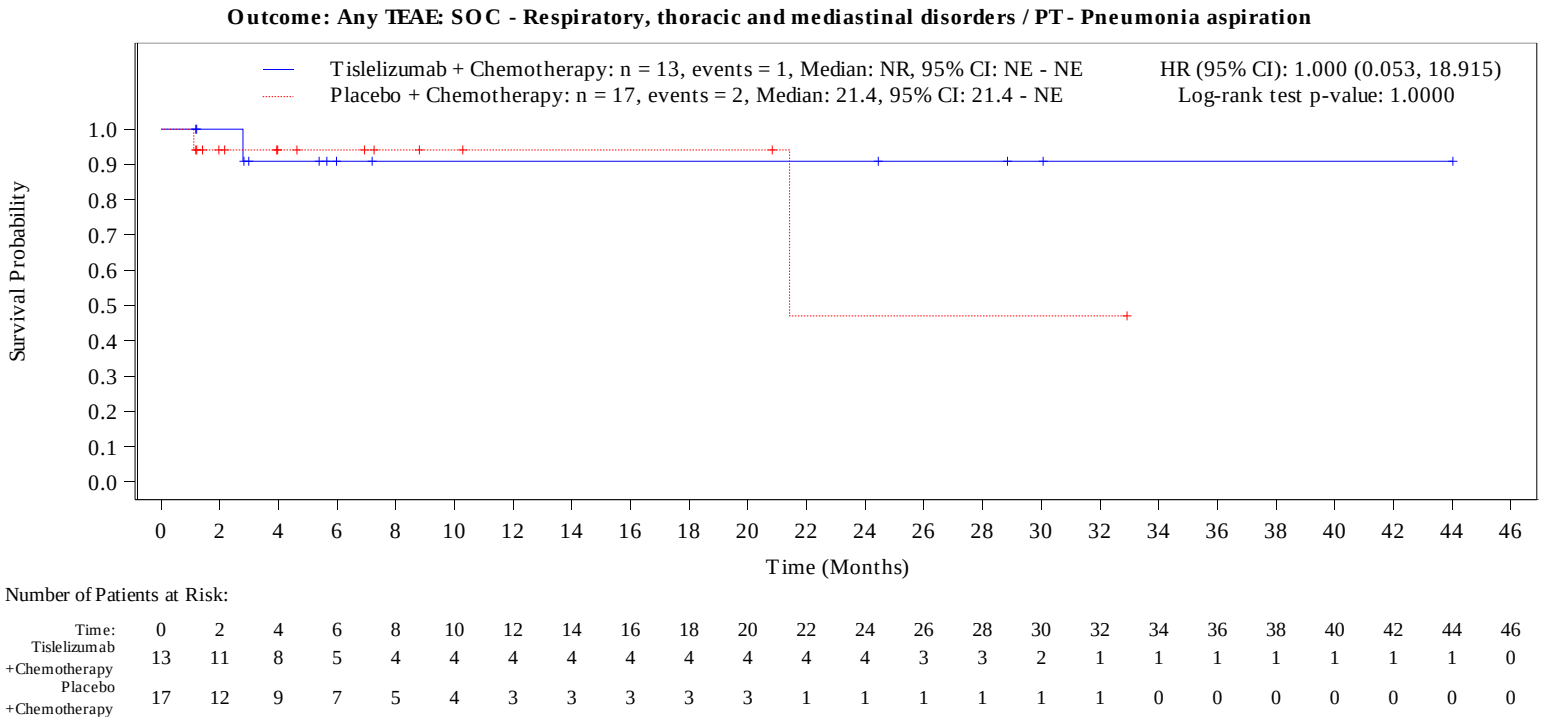

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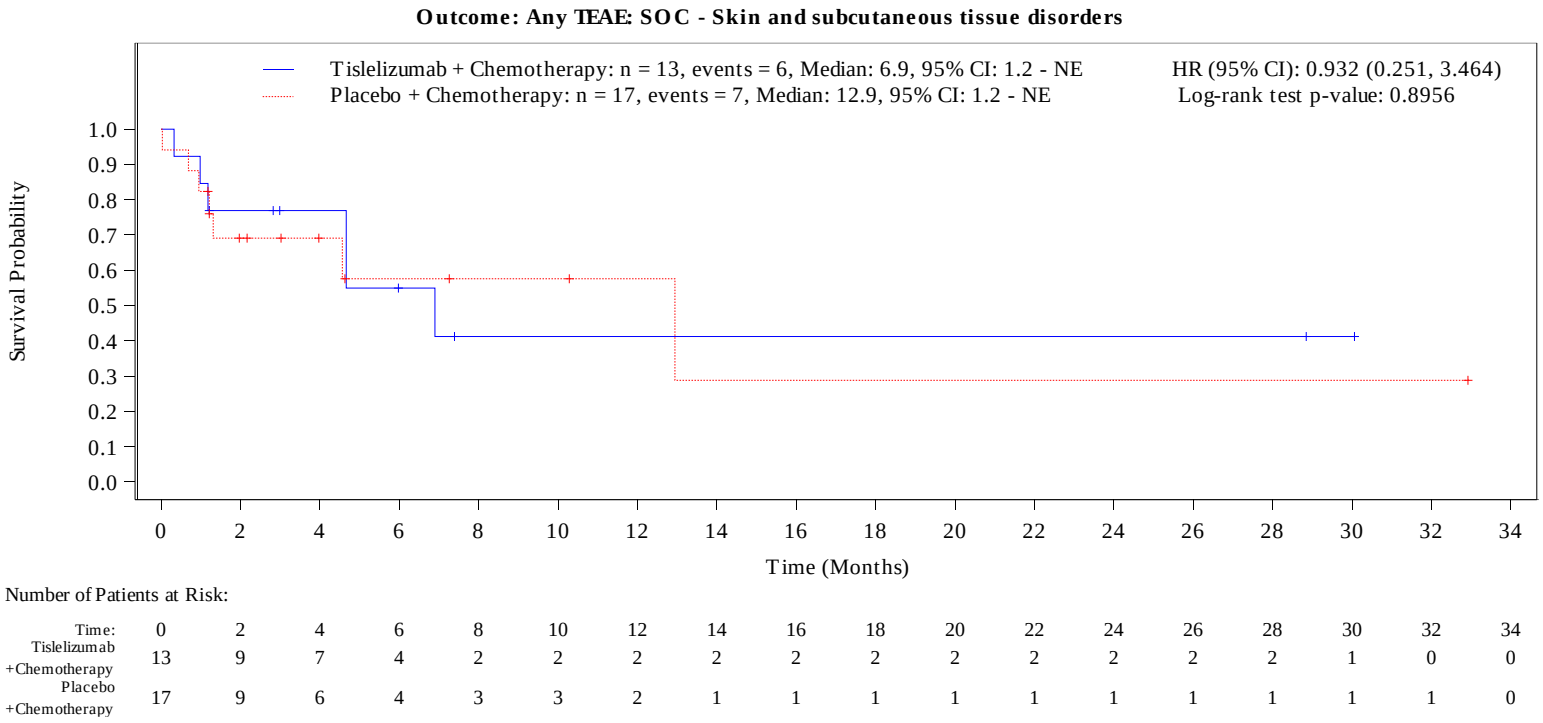

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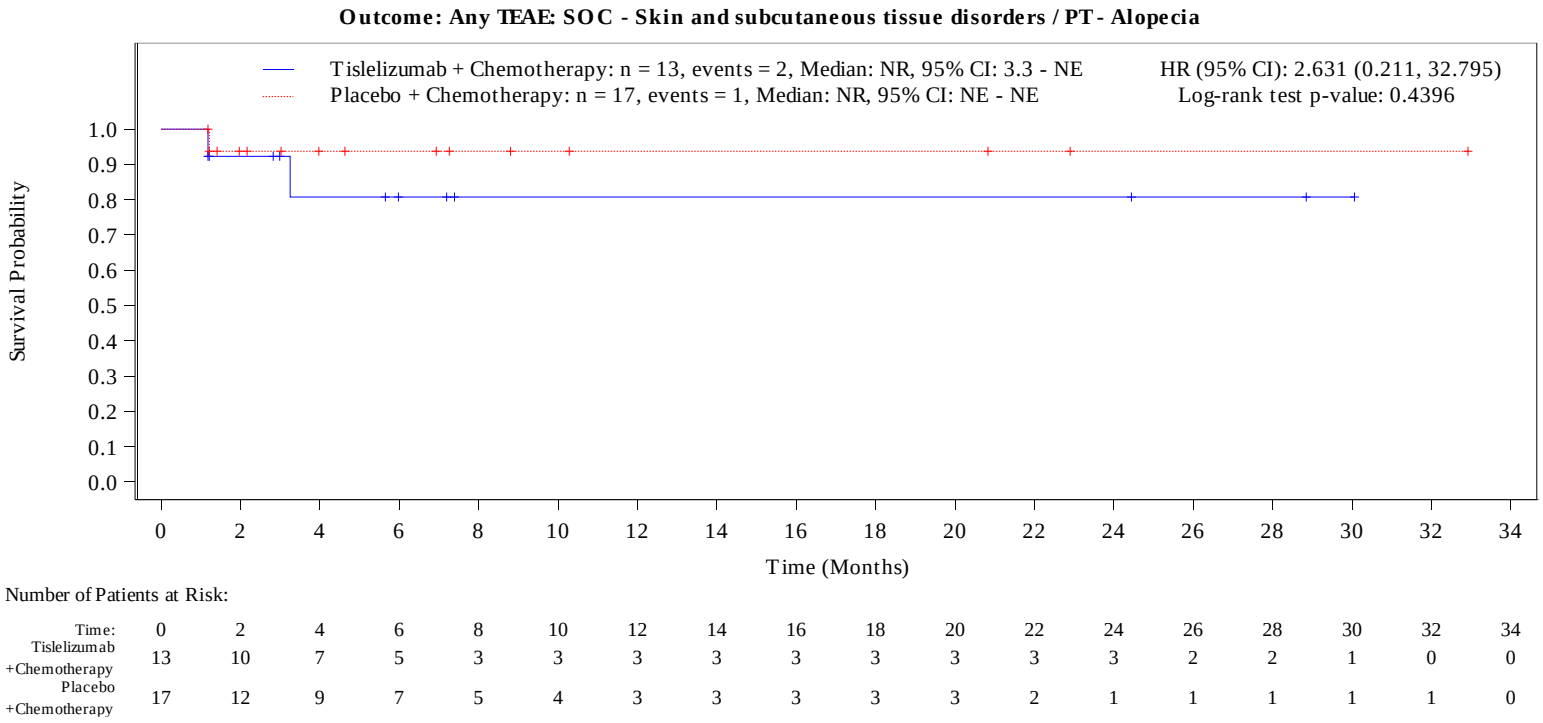

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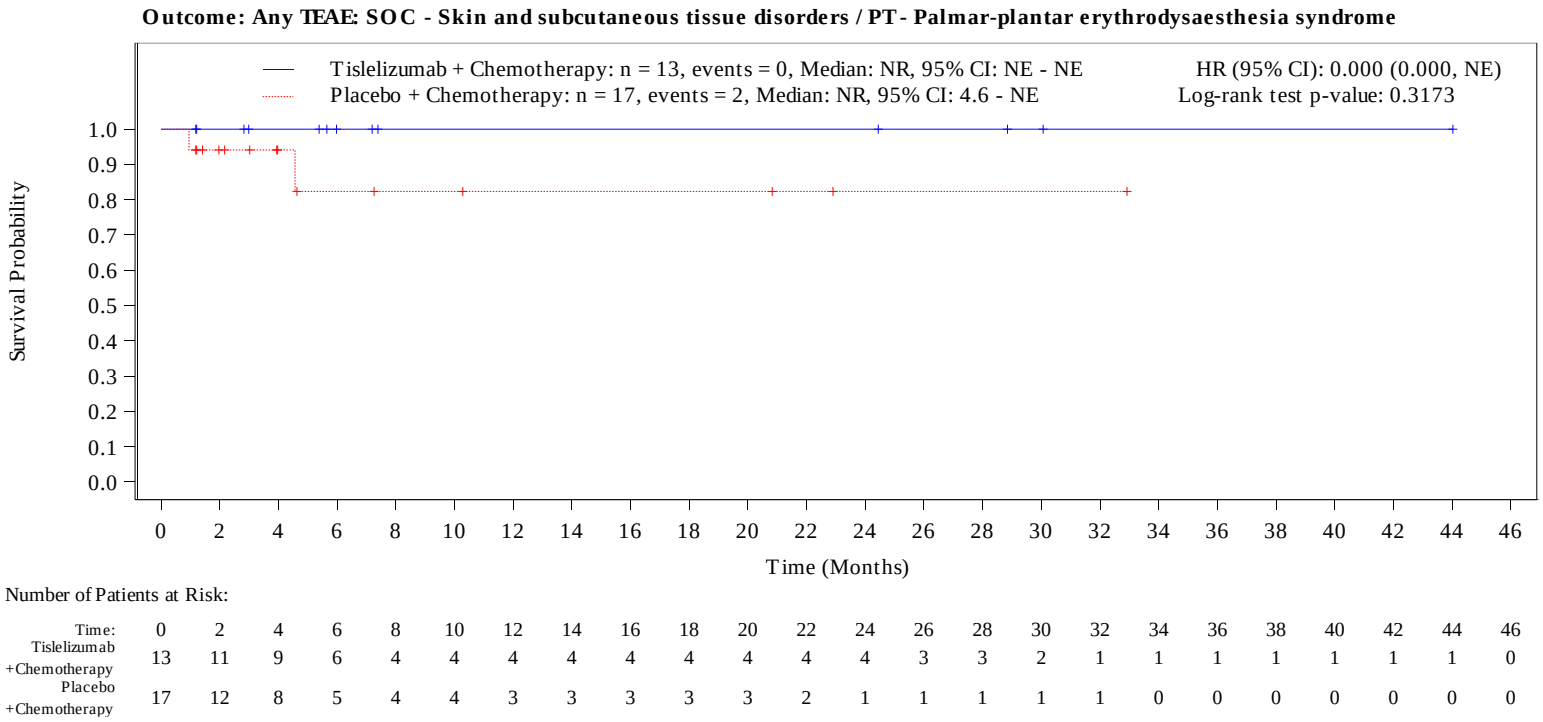

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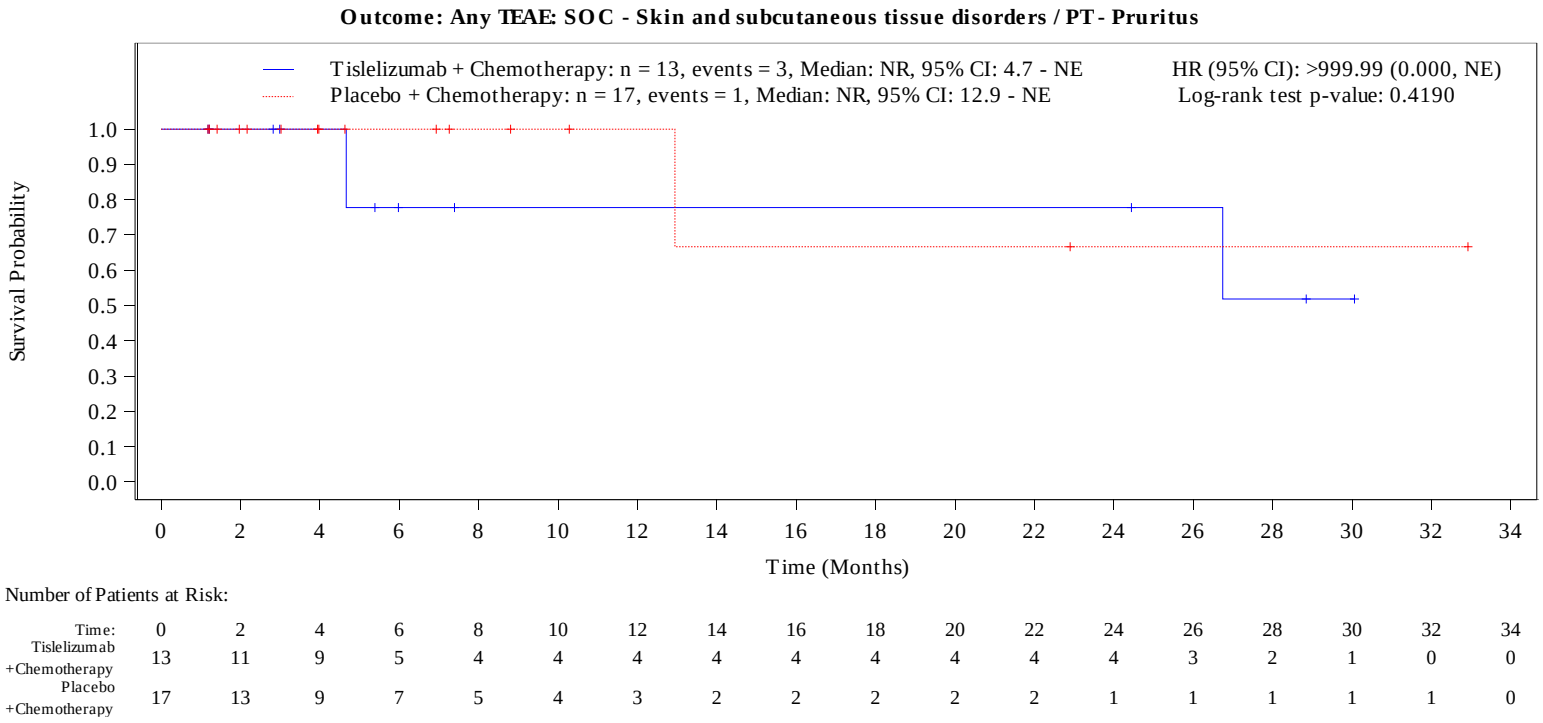

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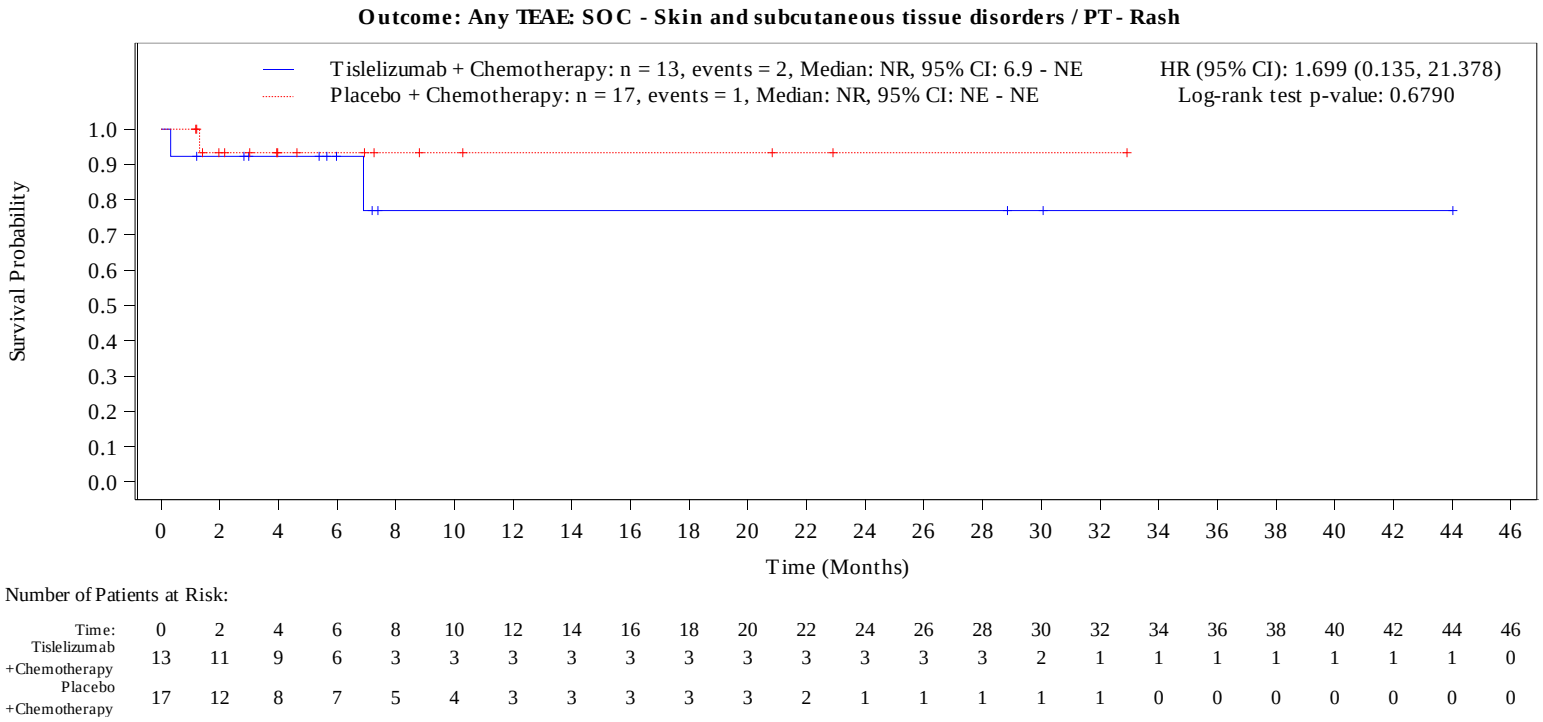

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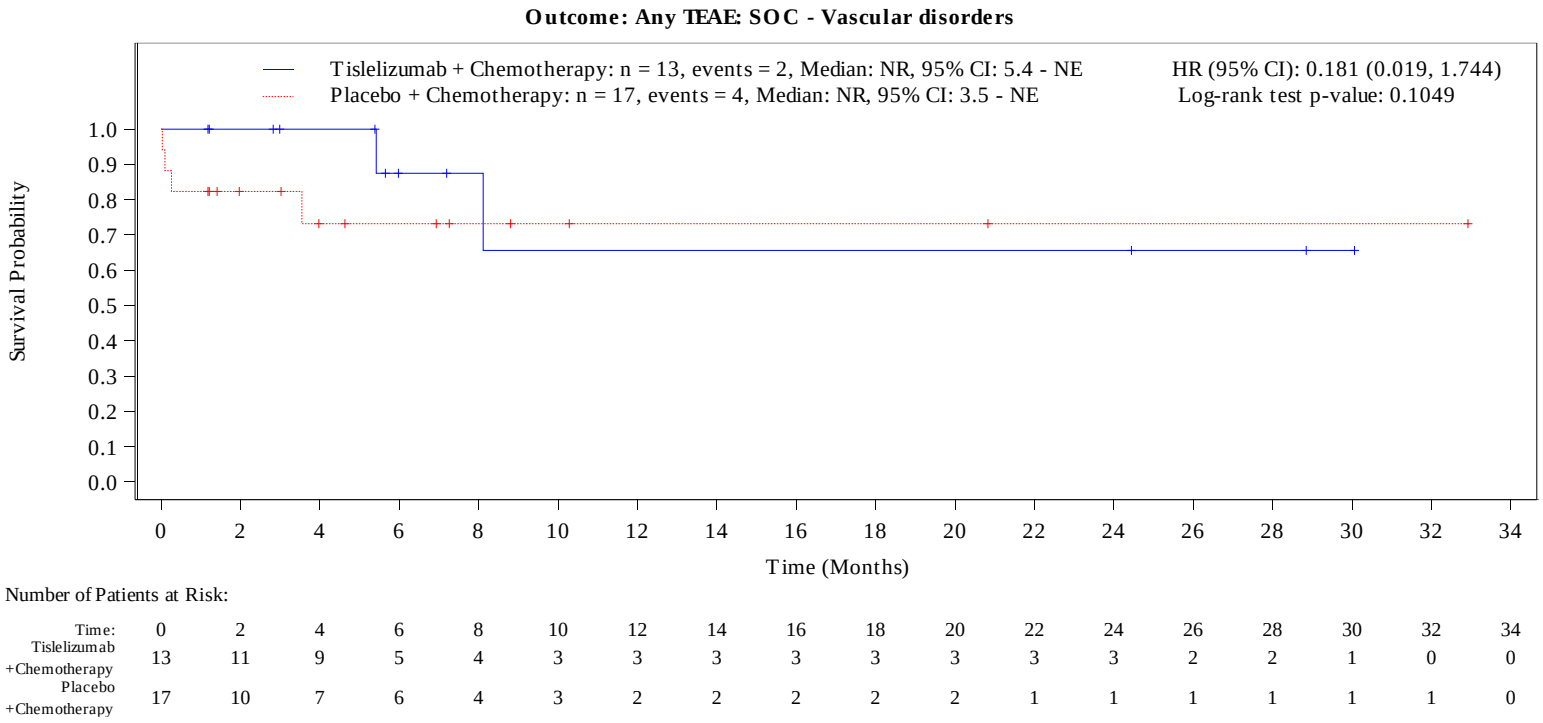

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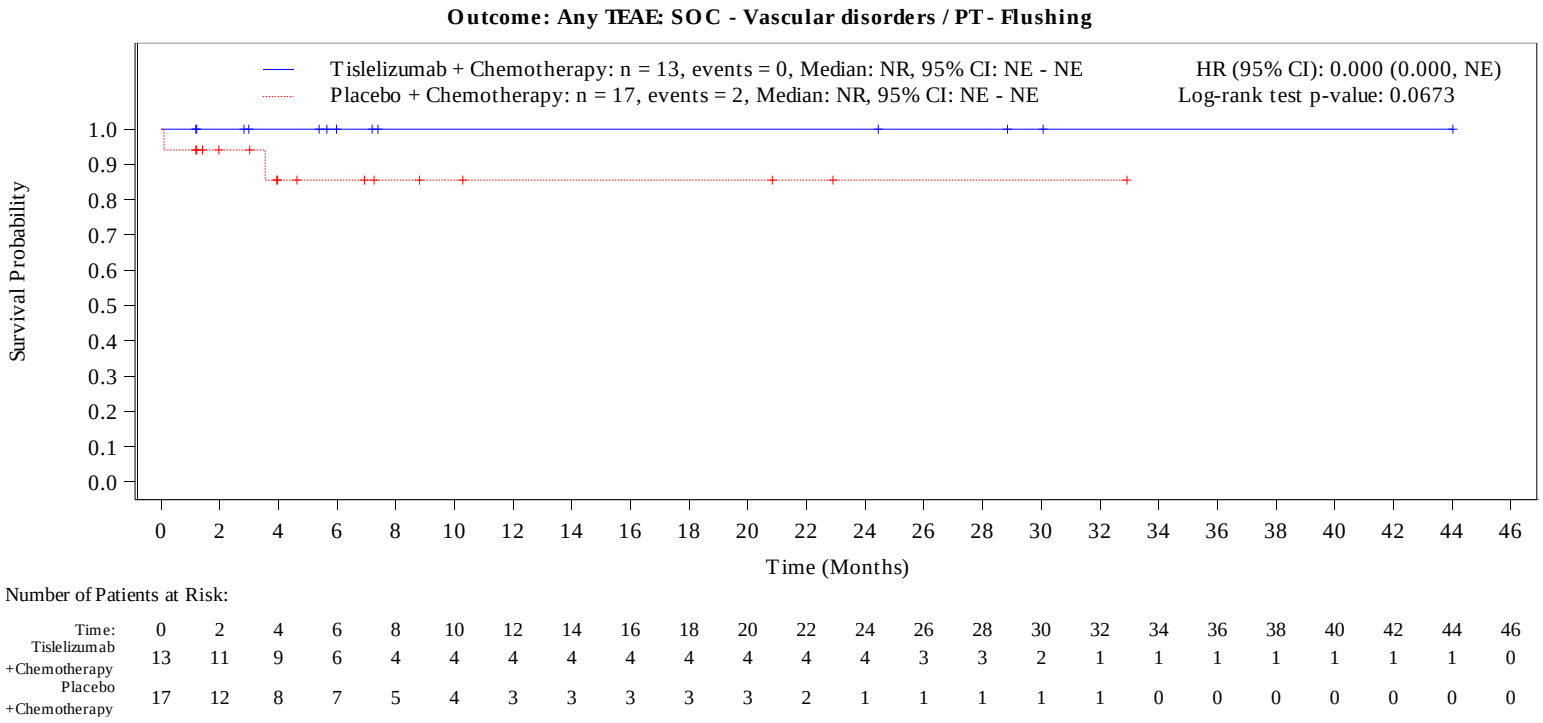

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

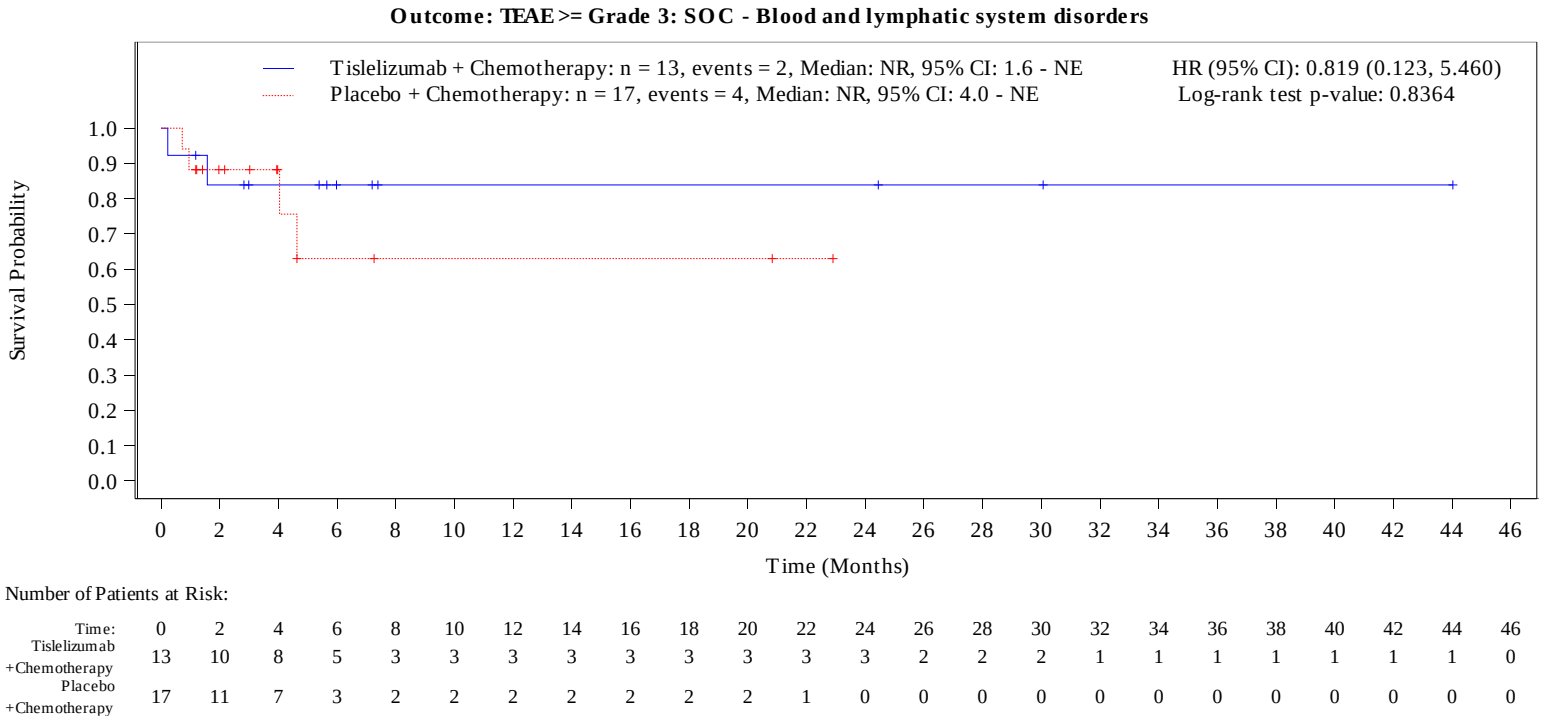

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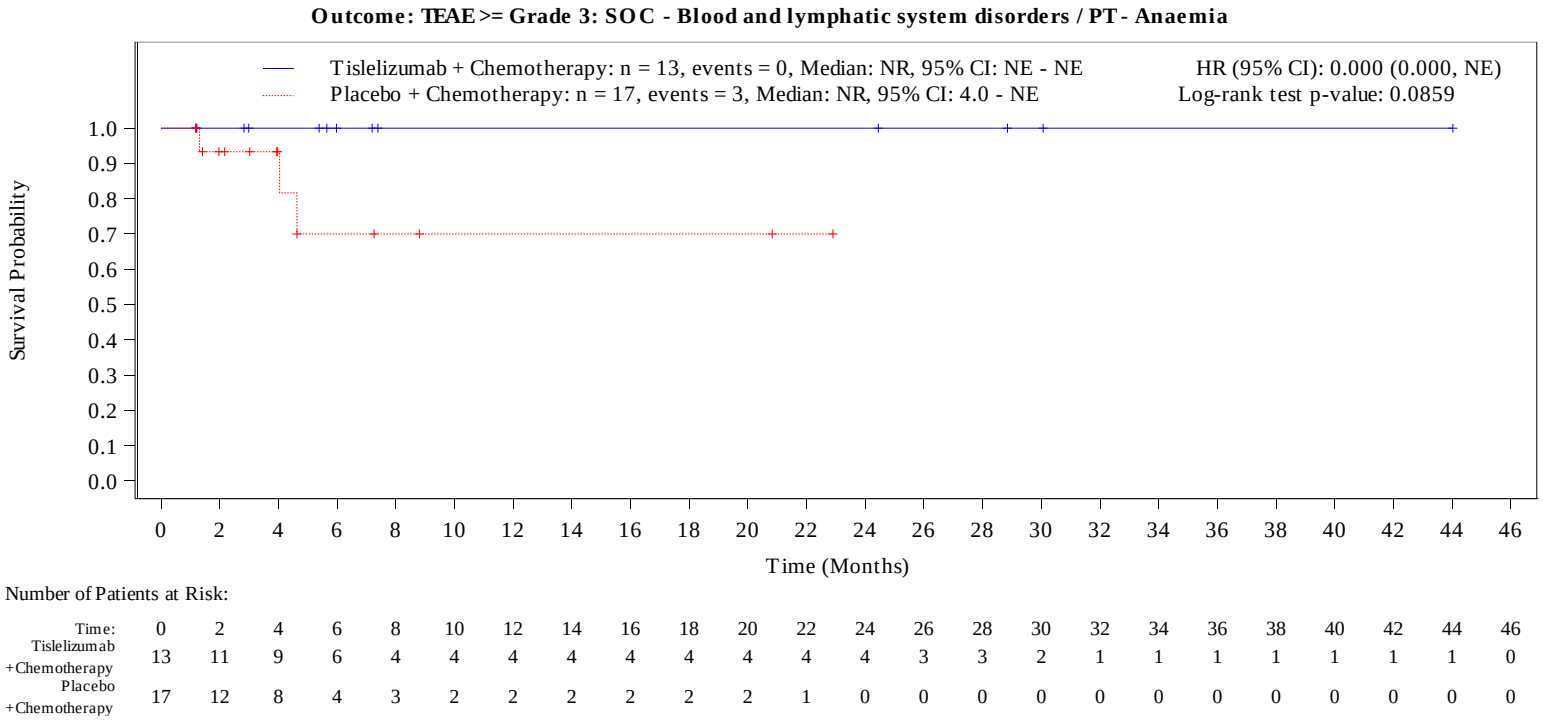
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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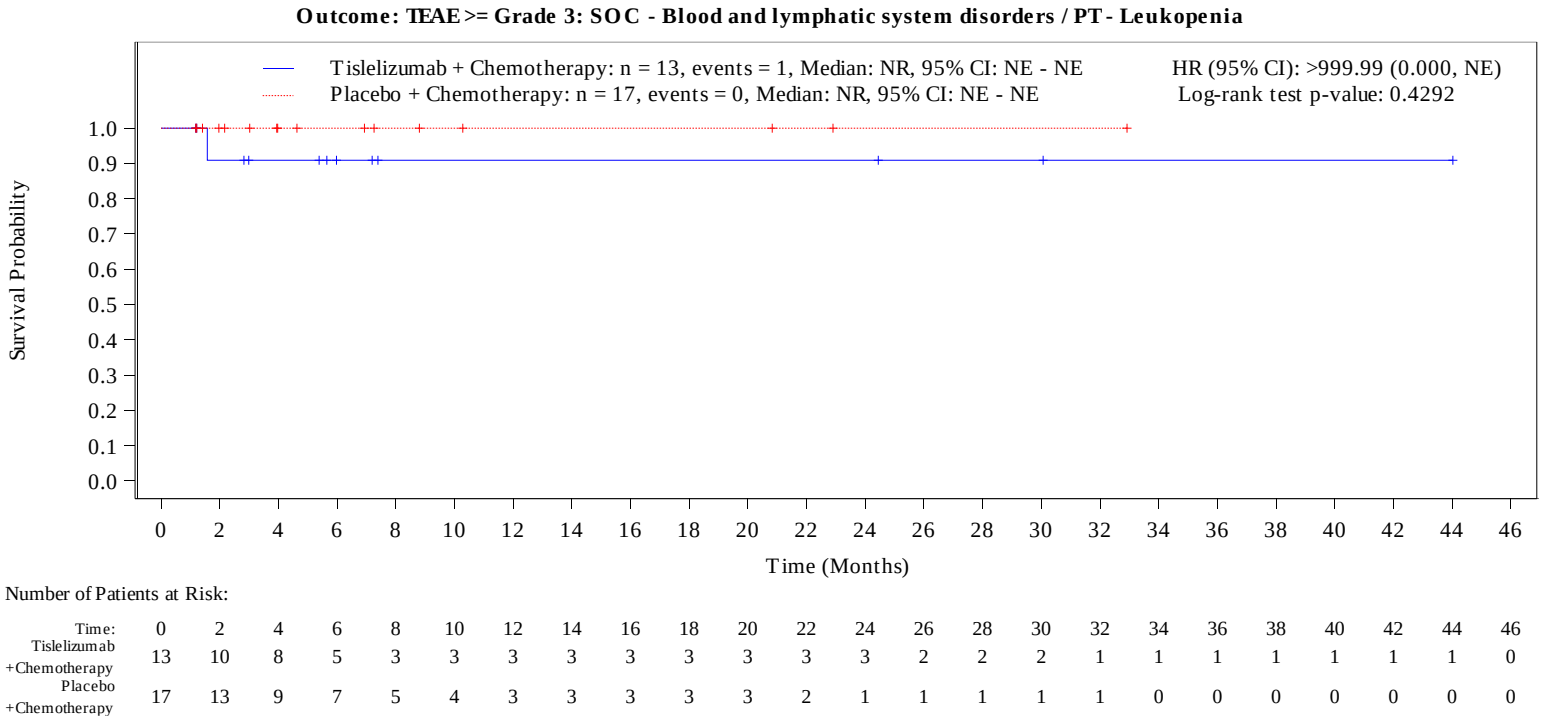

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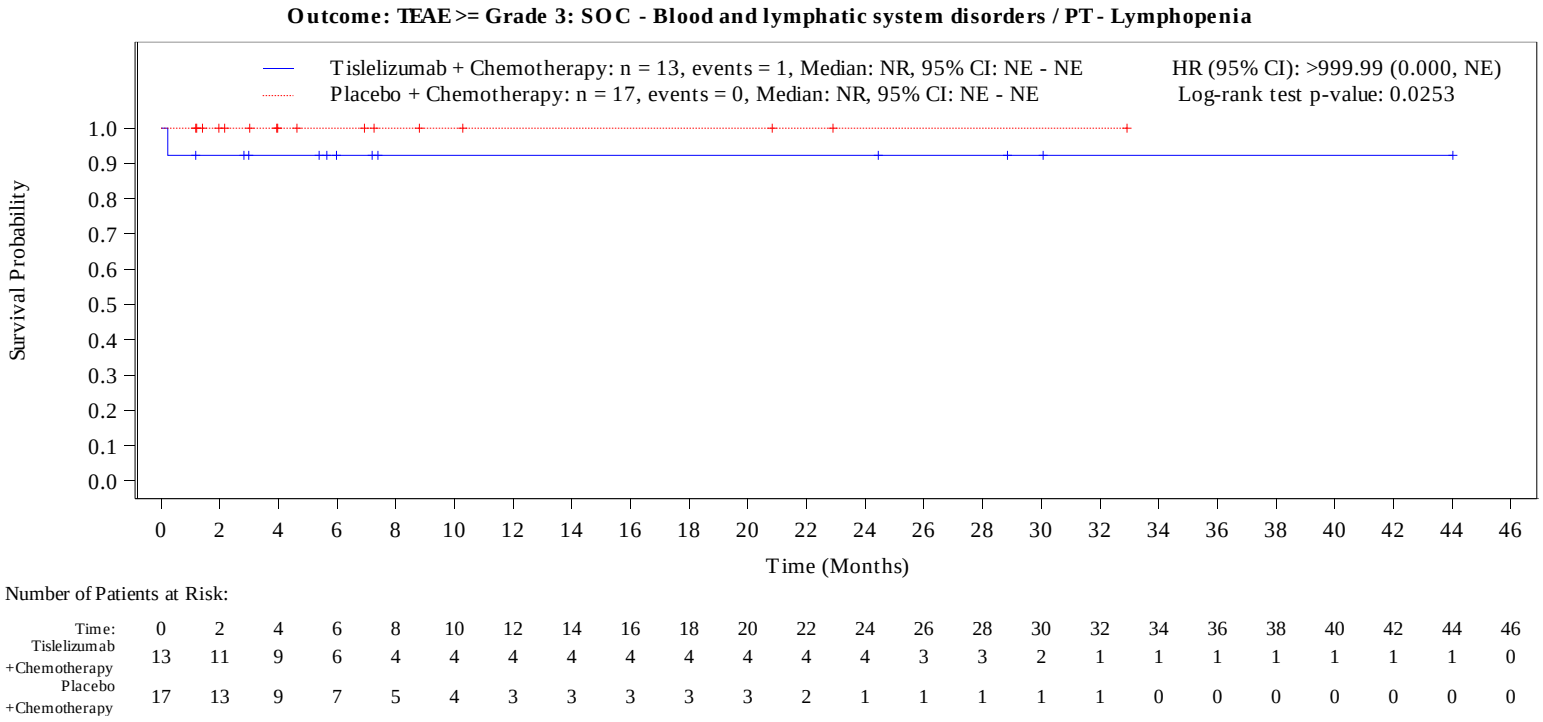

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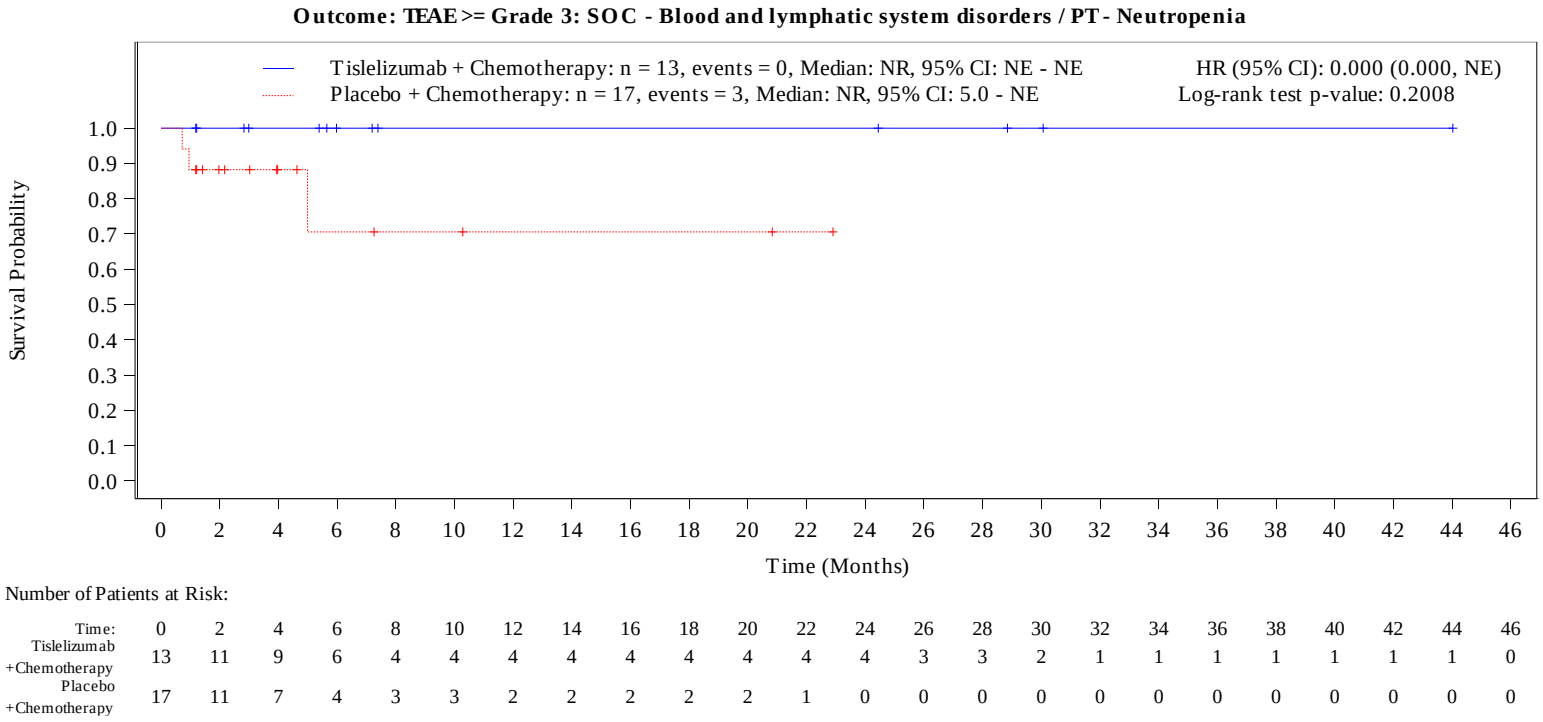

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	7	4	3	3	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0

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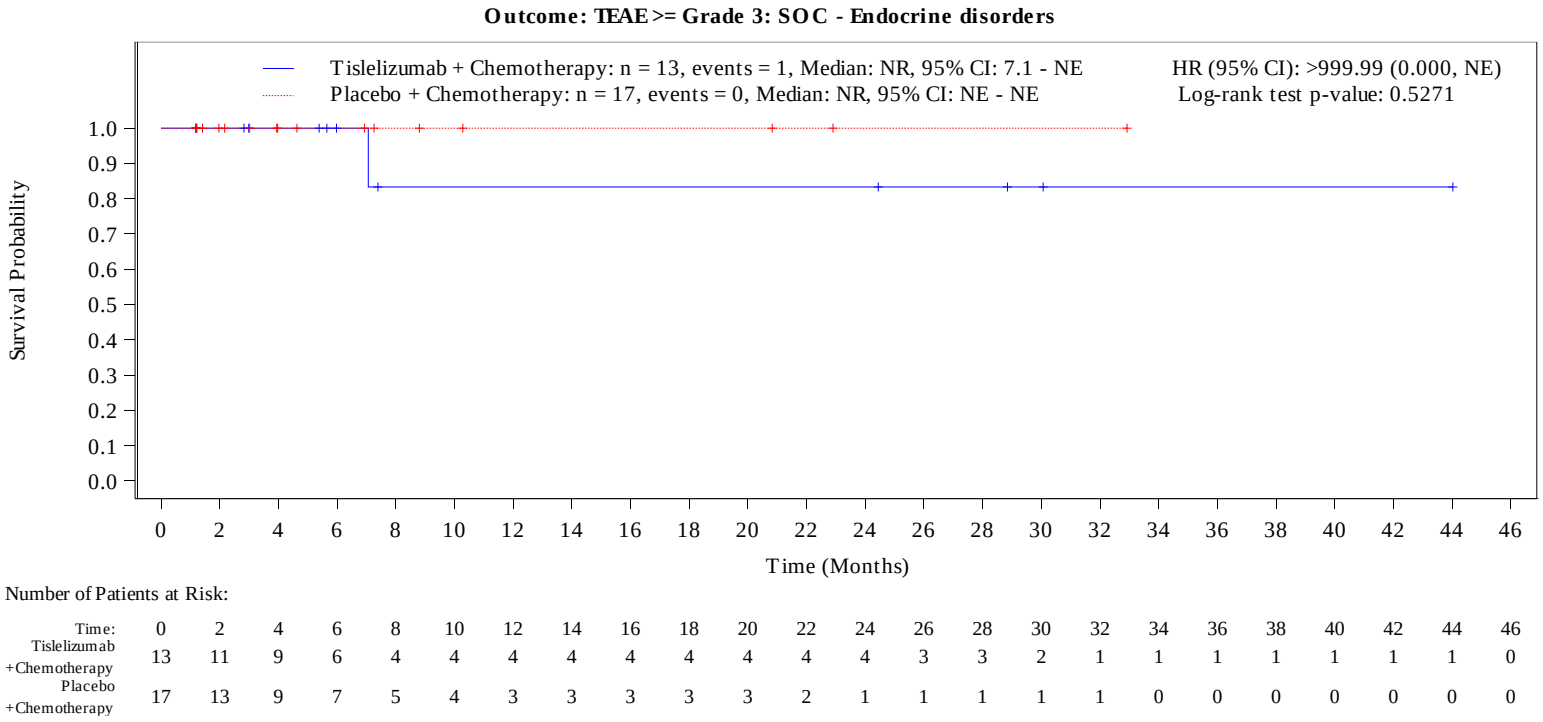

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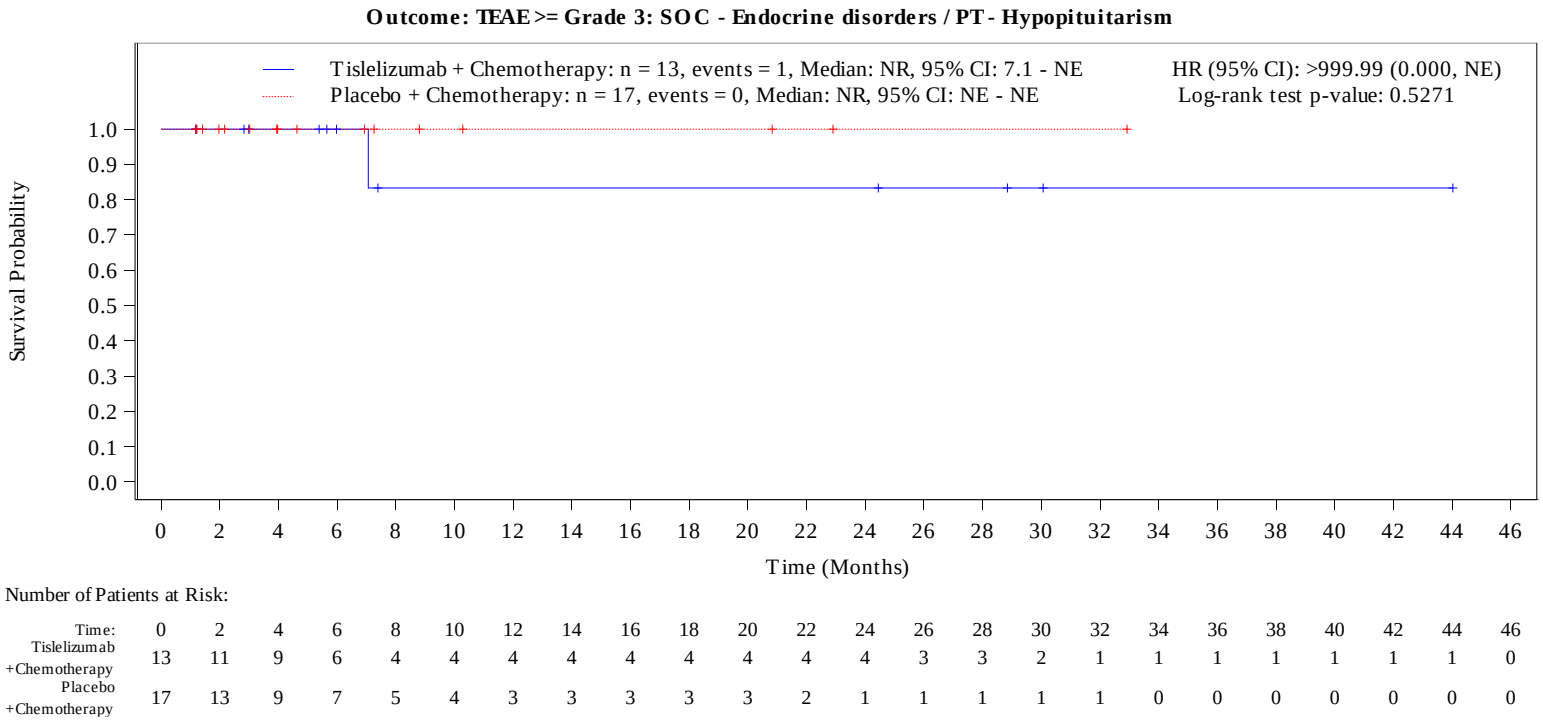
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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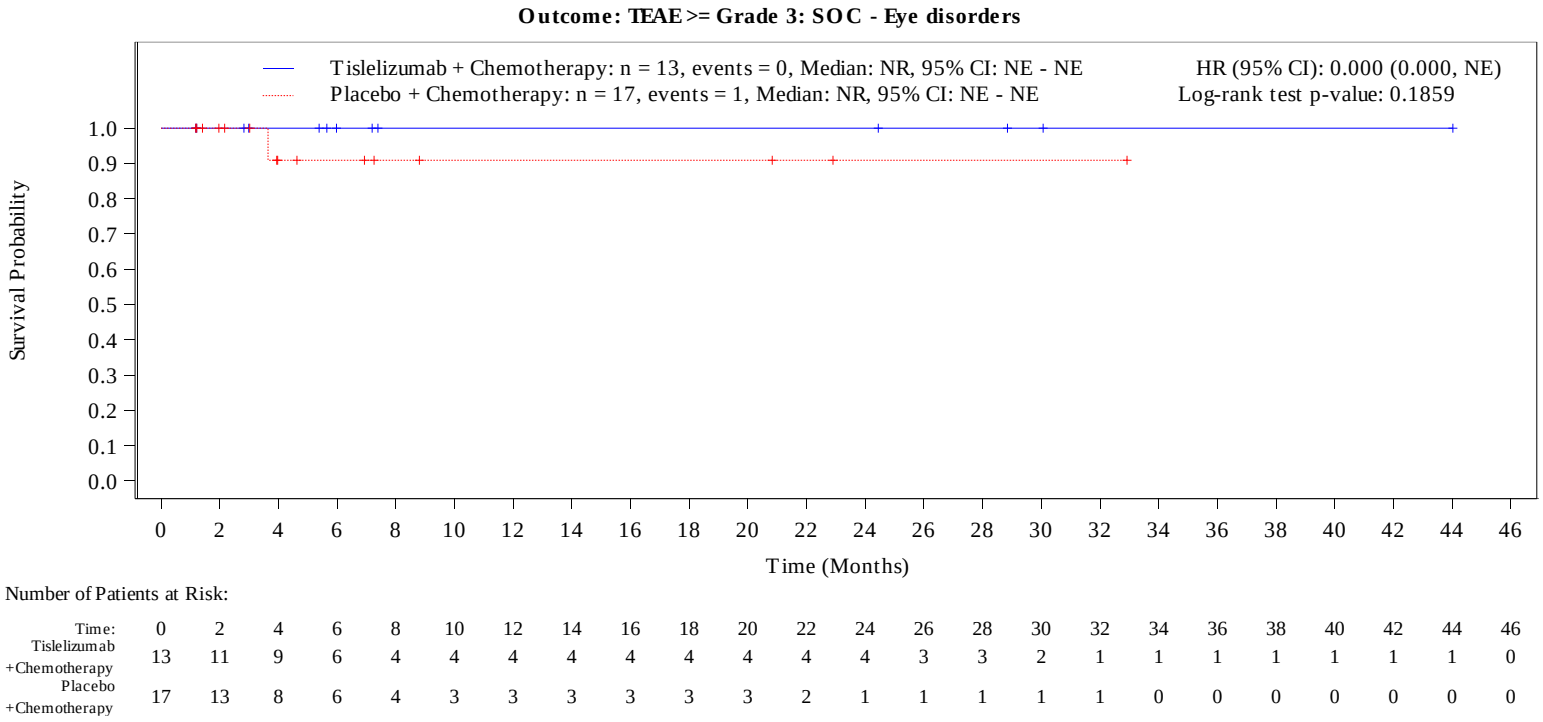

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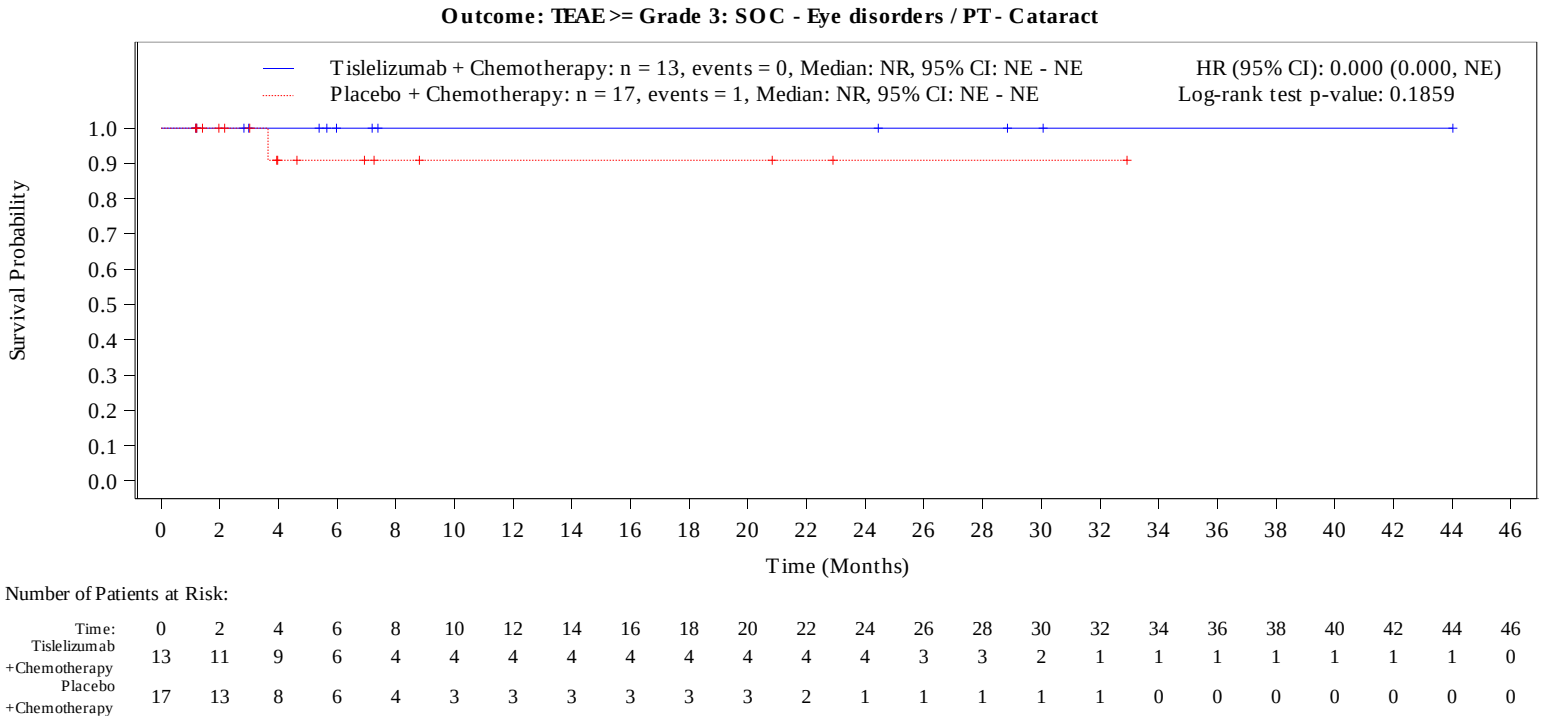

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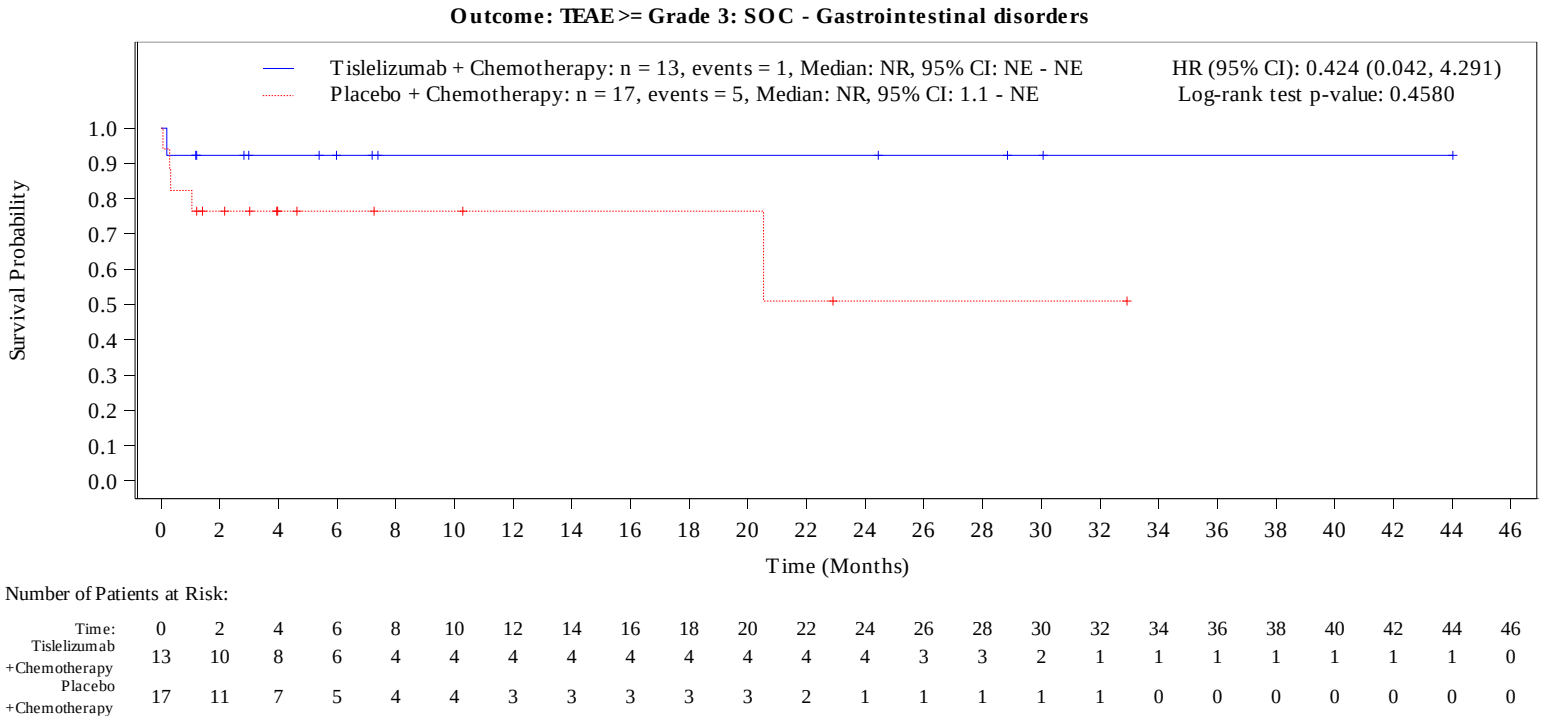

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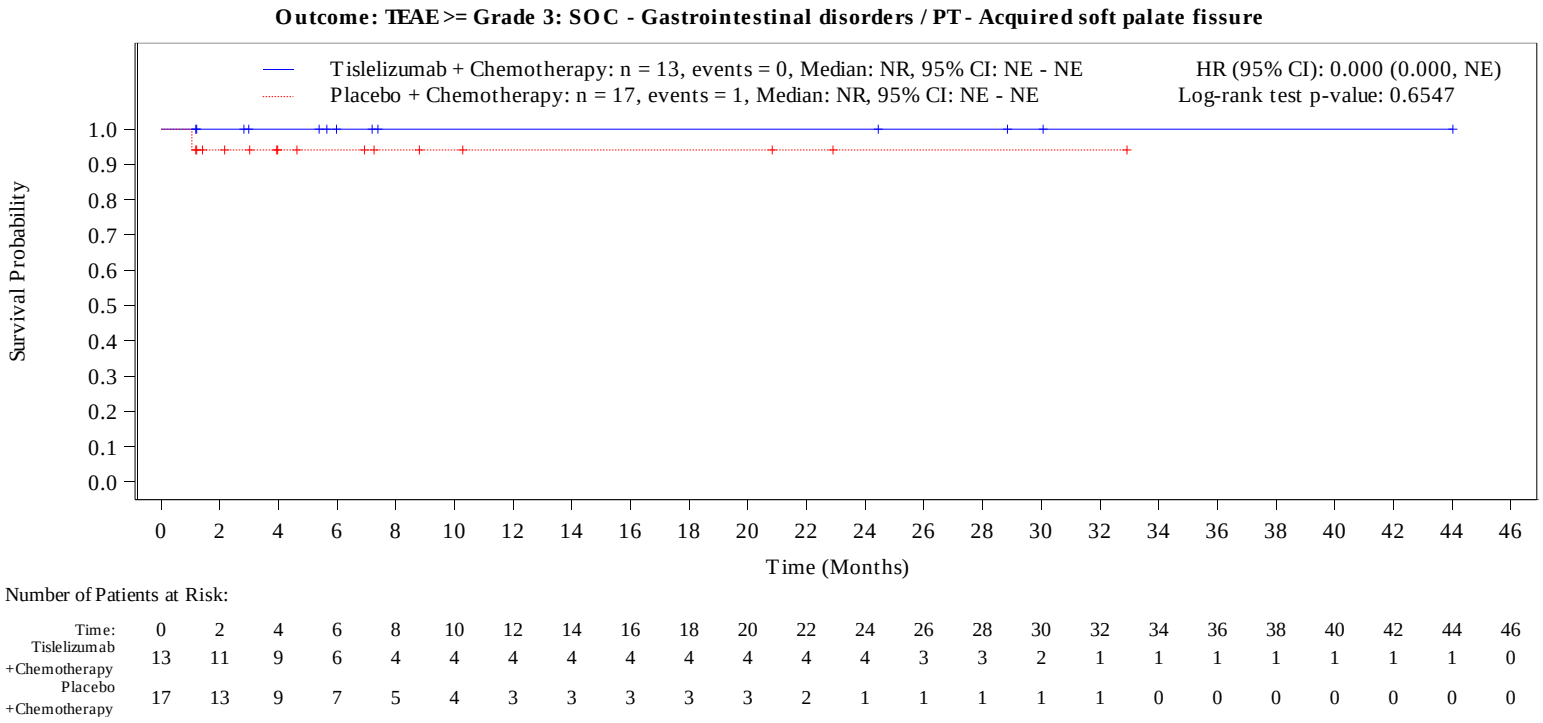

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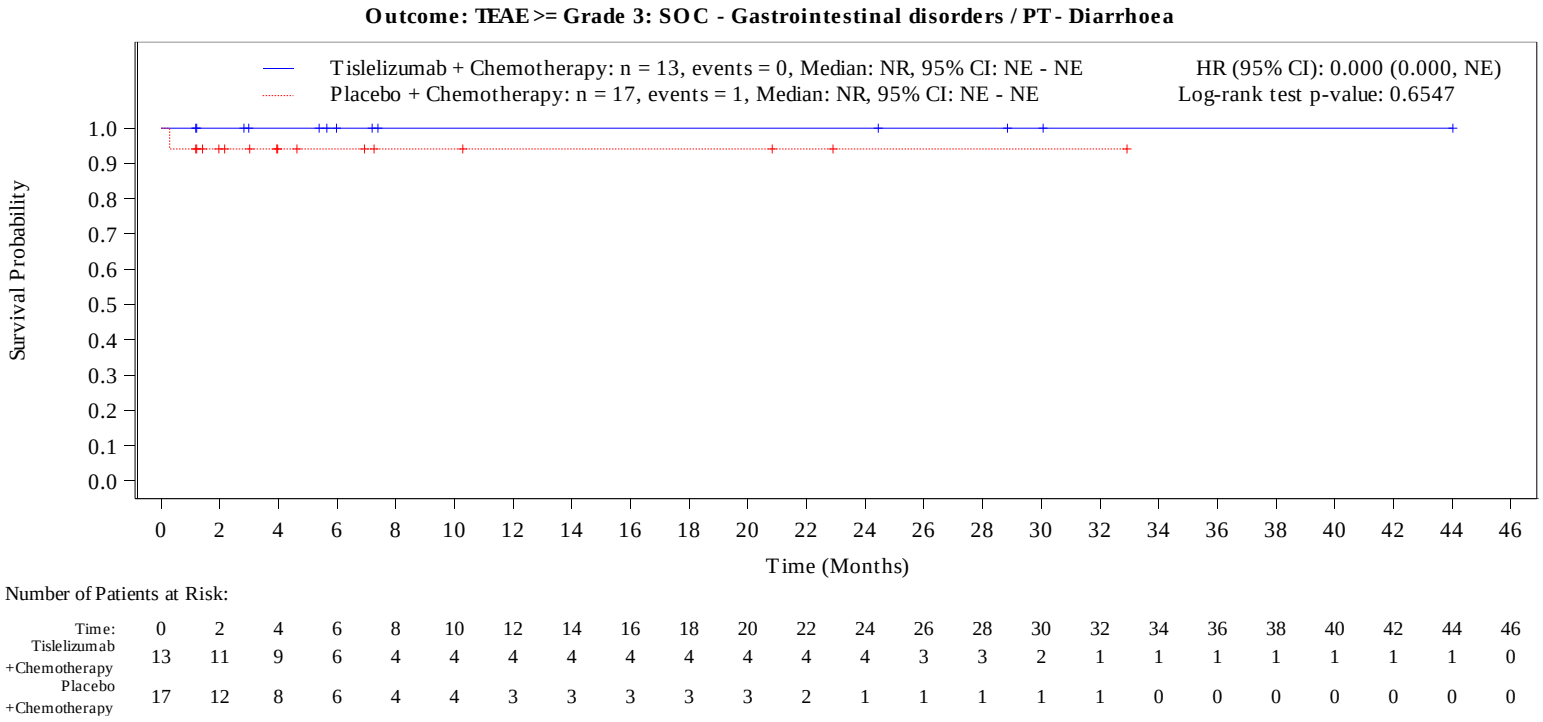

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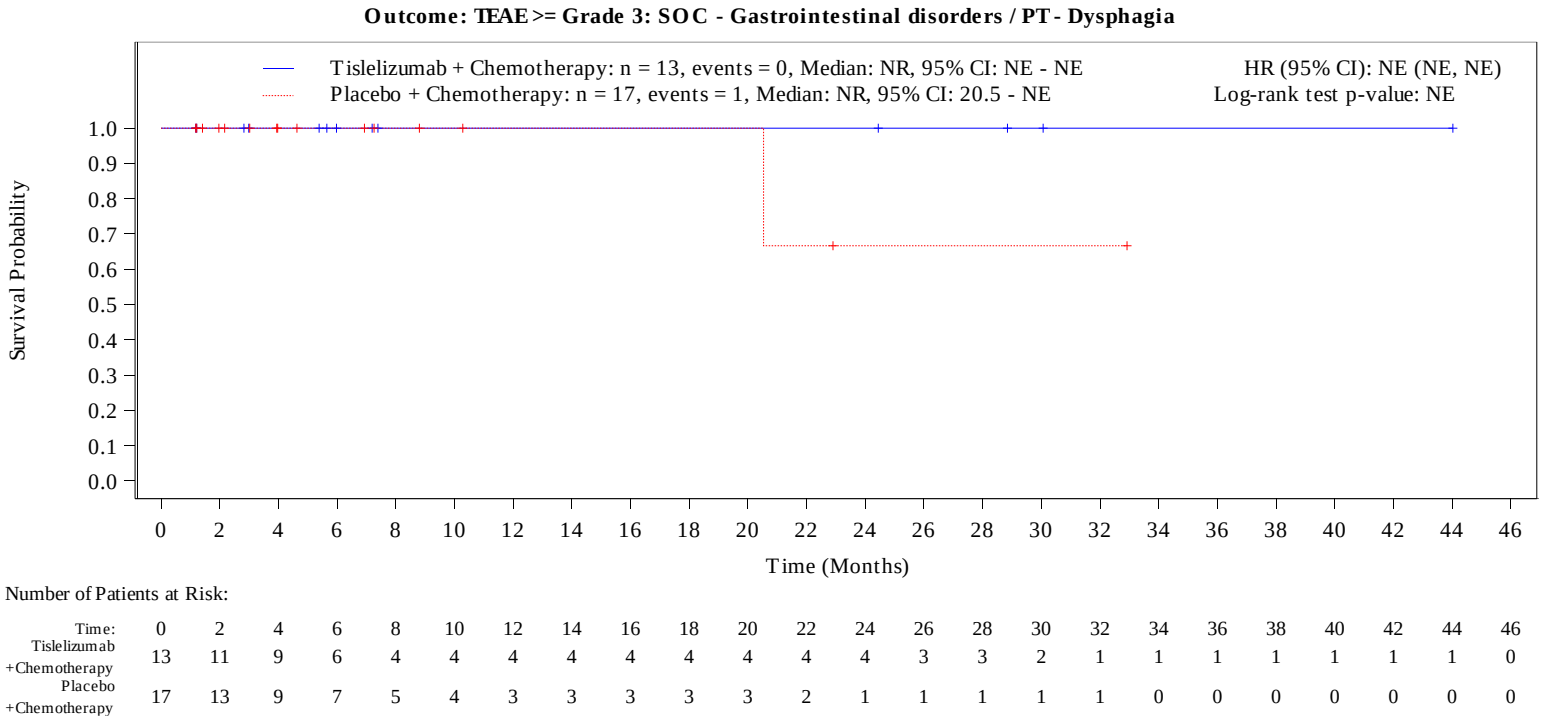

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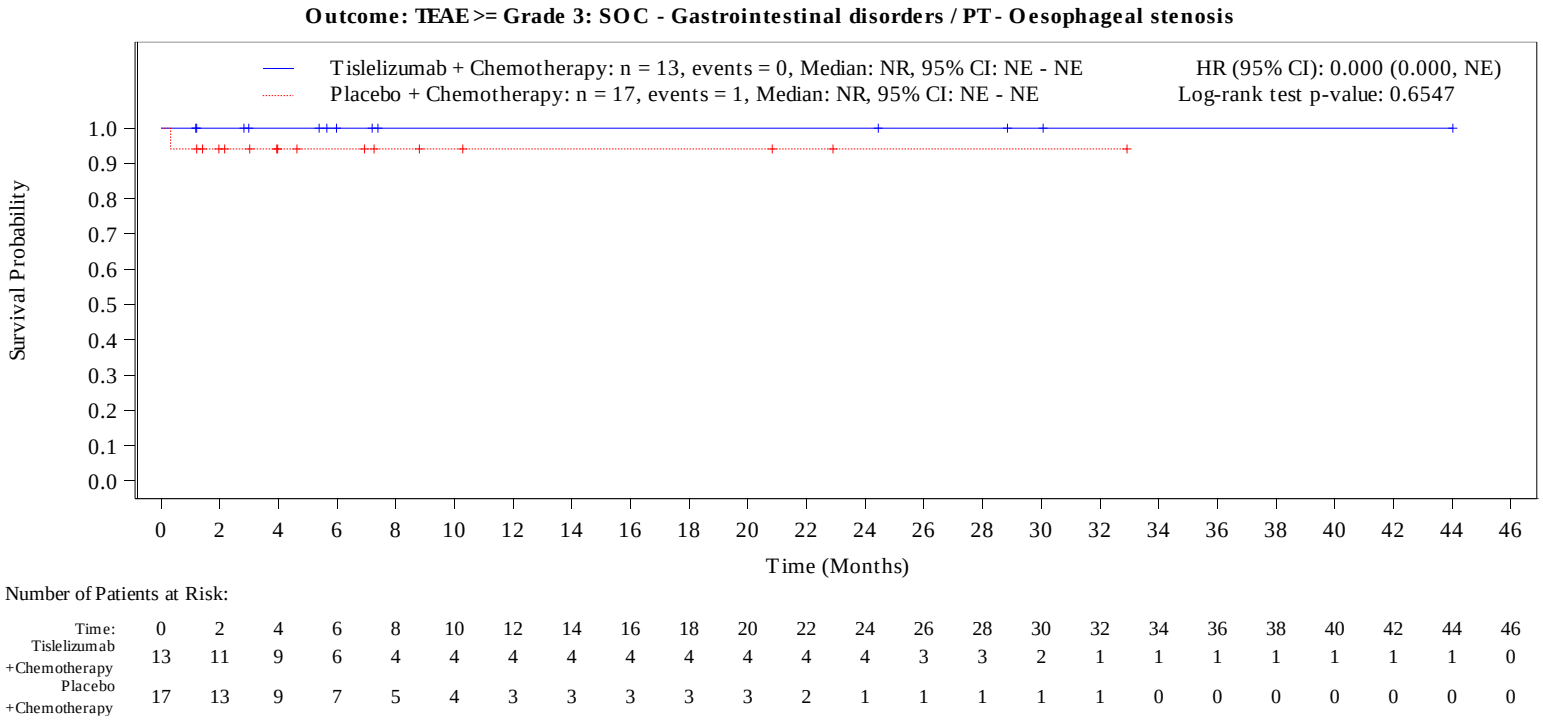

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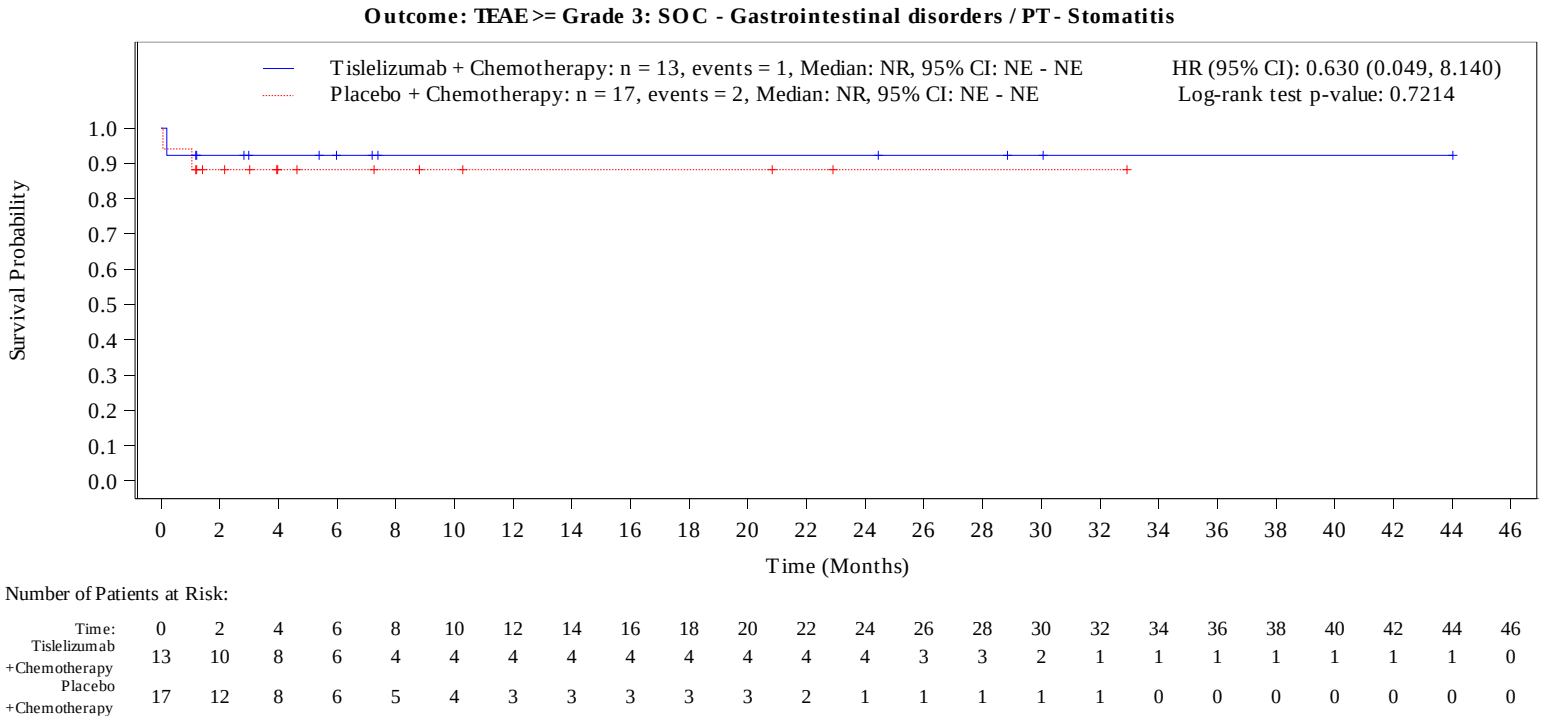

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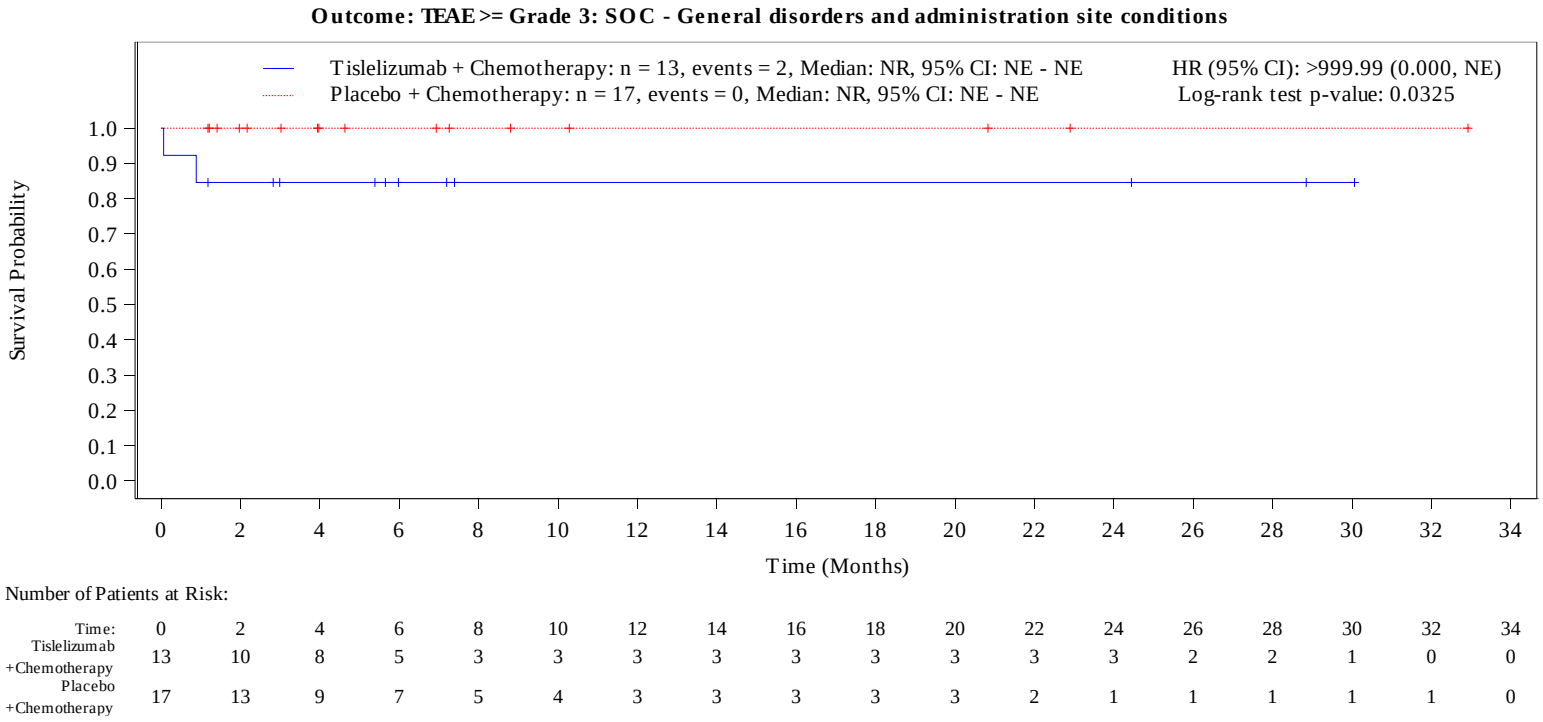

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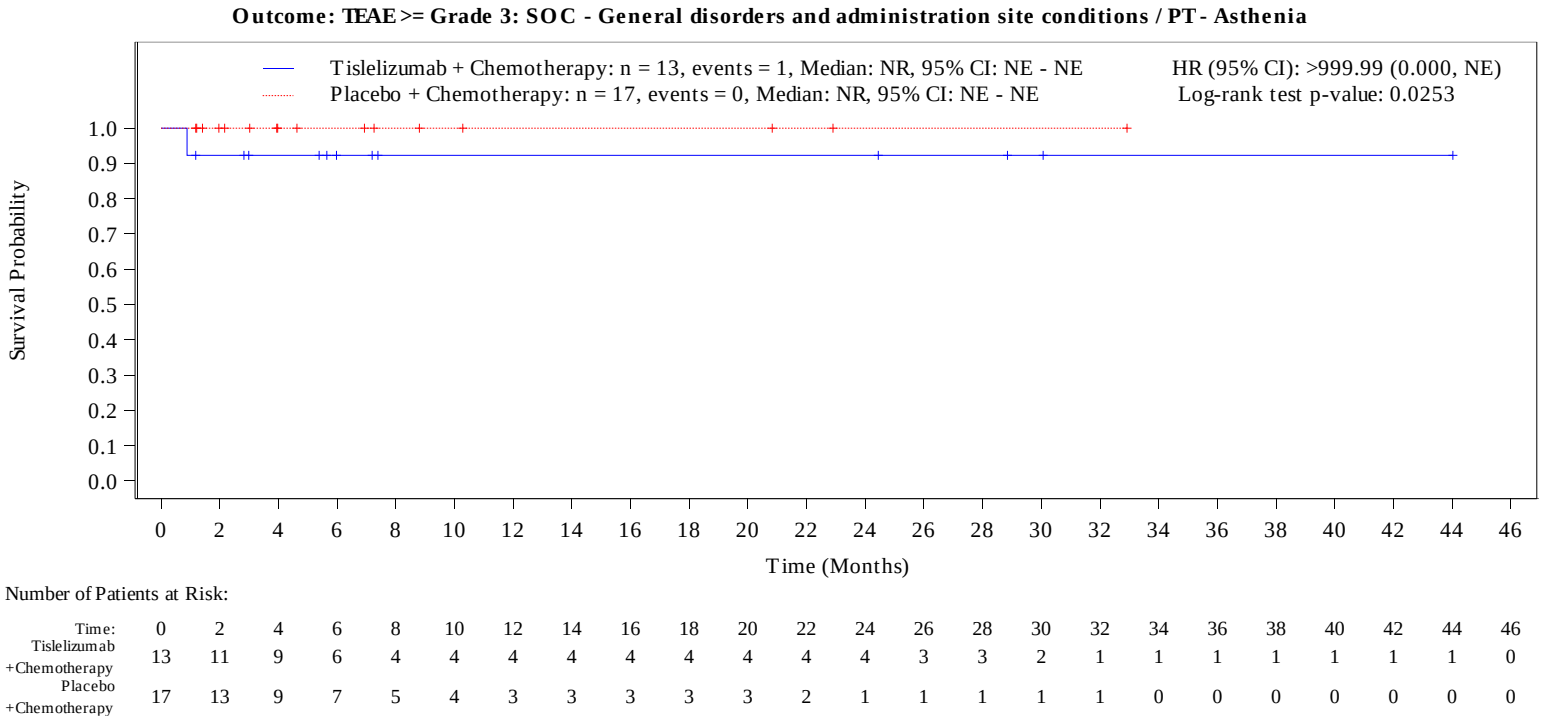

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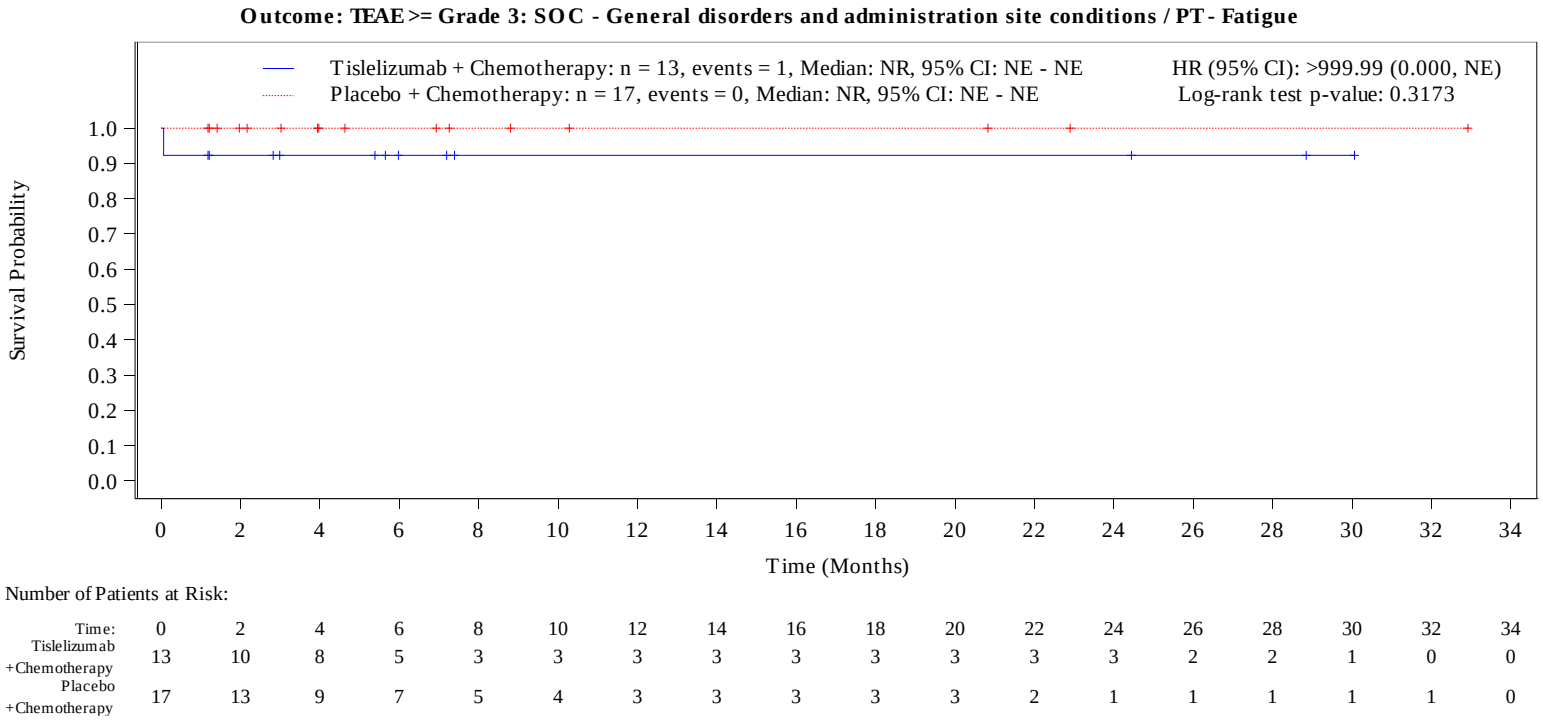

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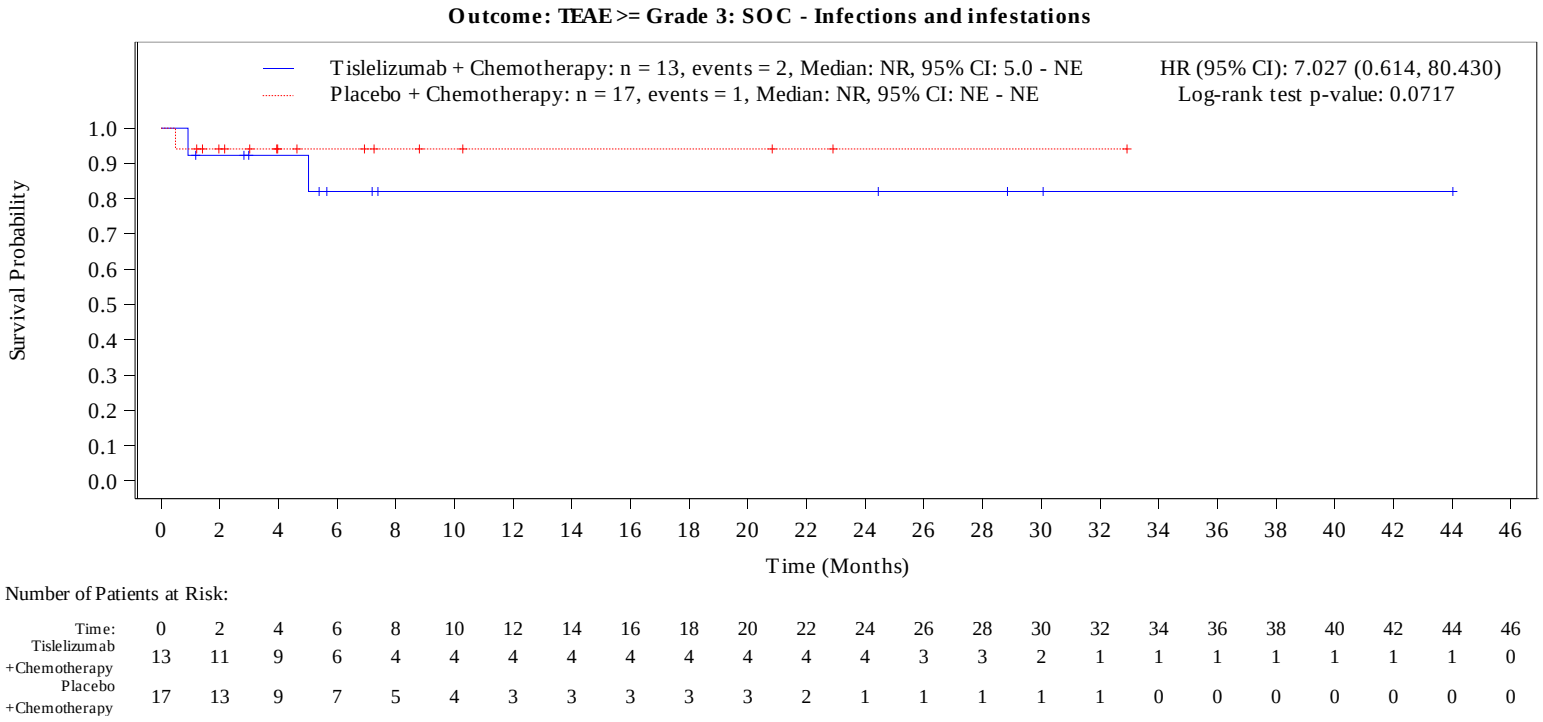

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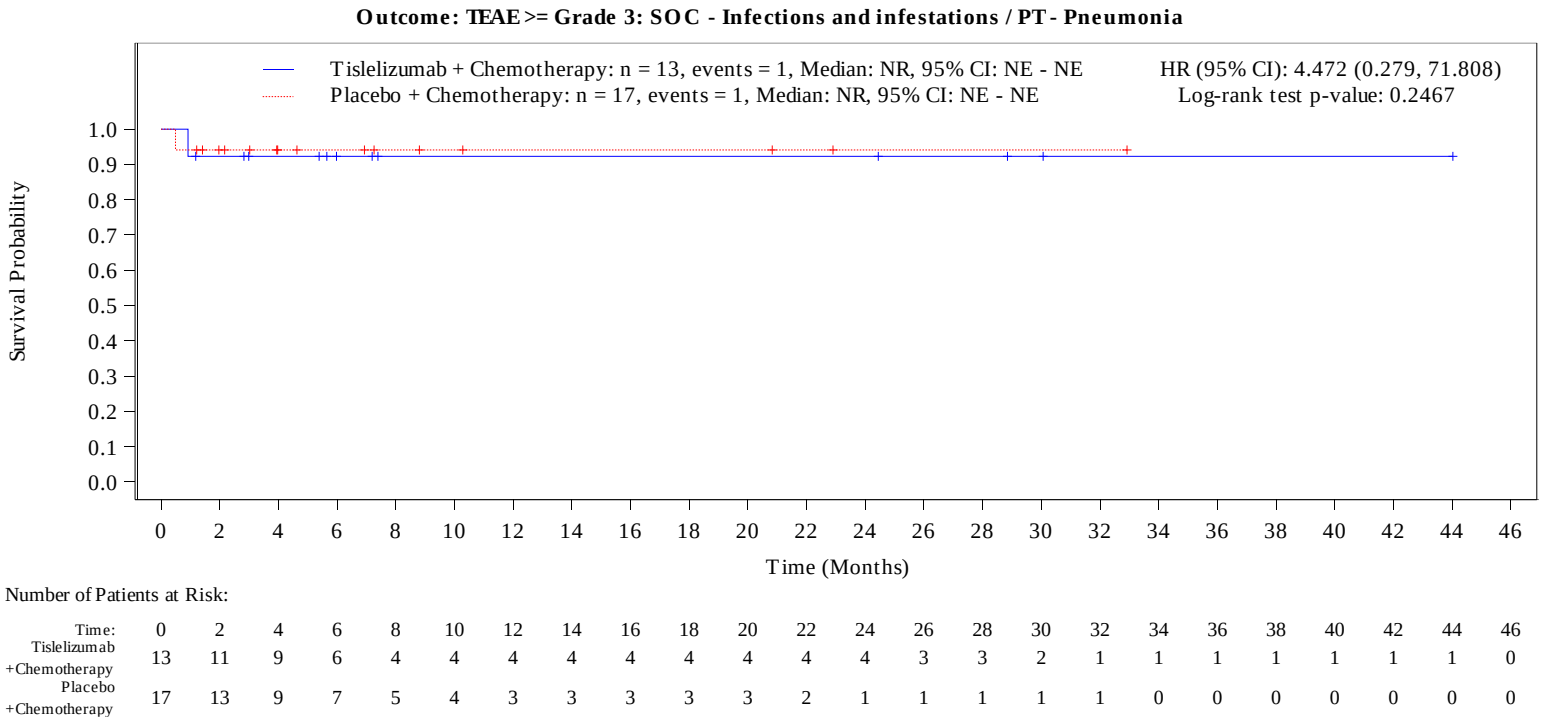

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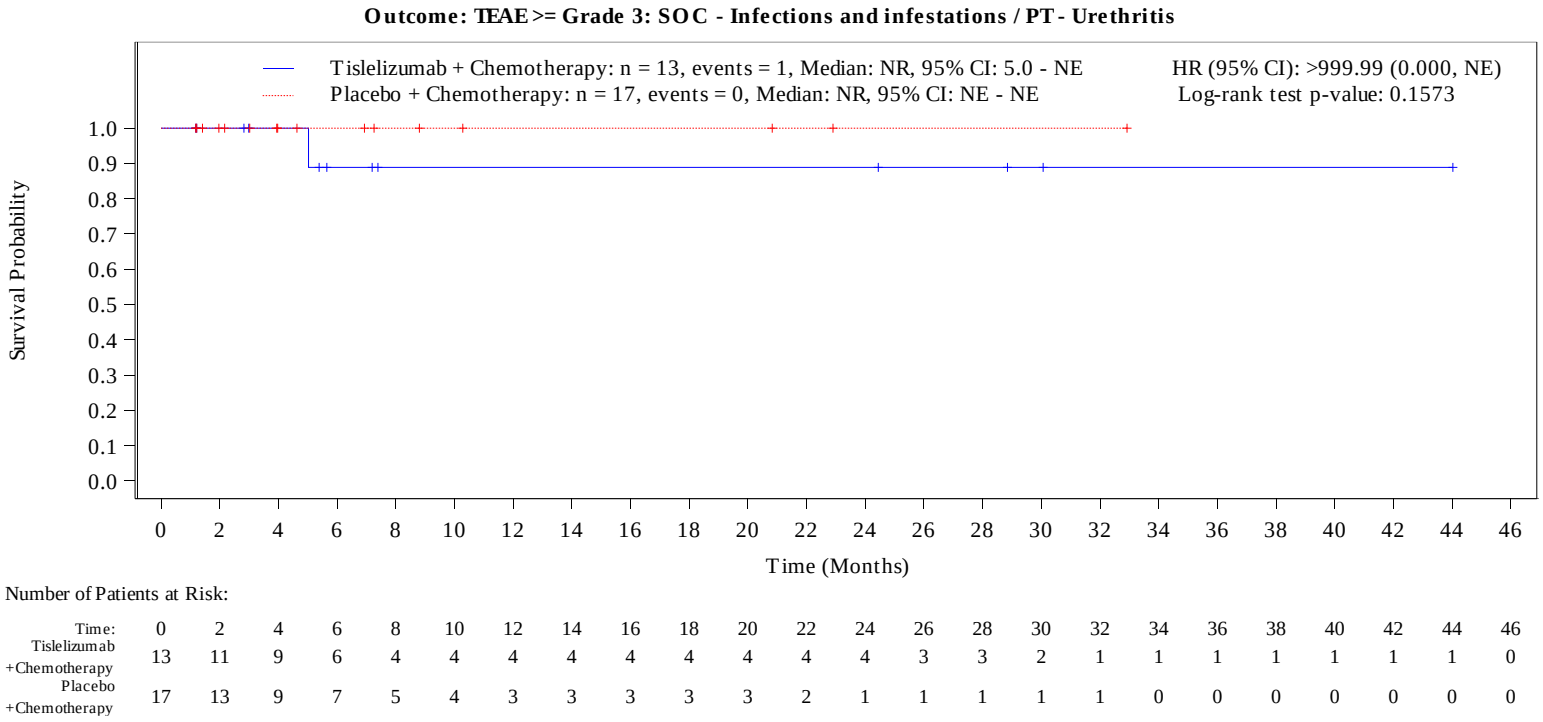

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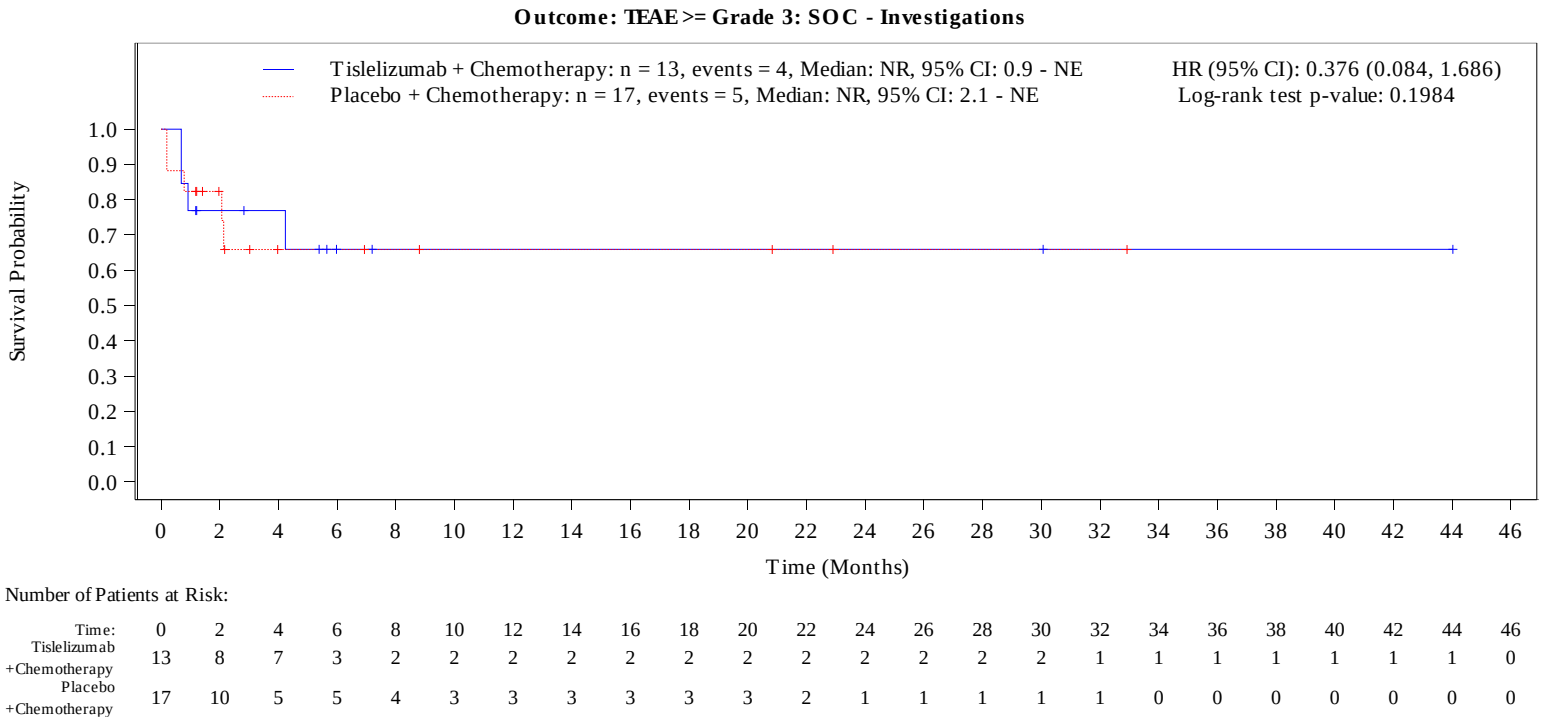

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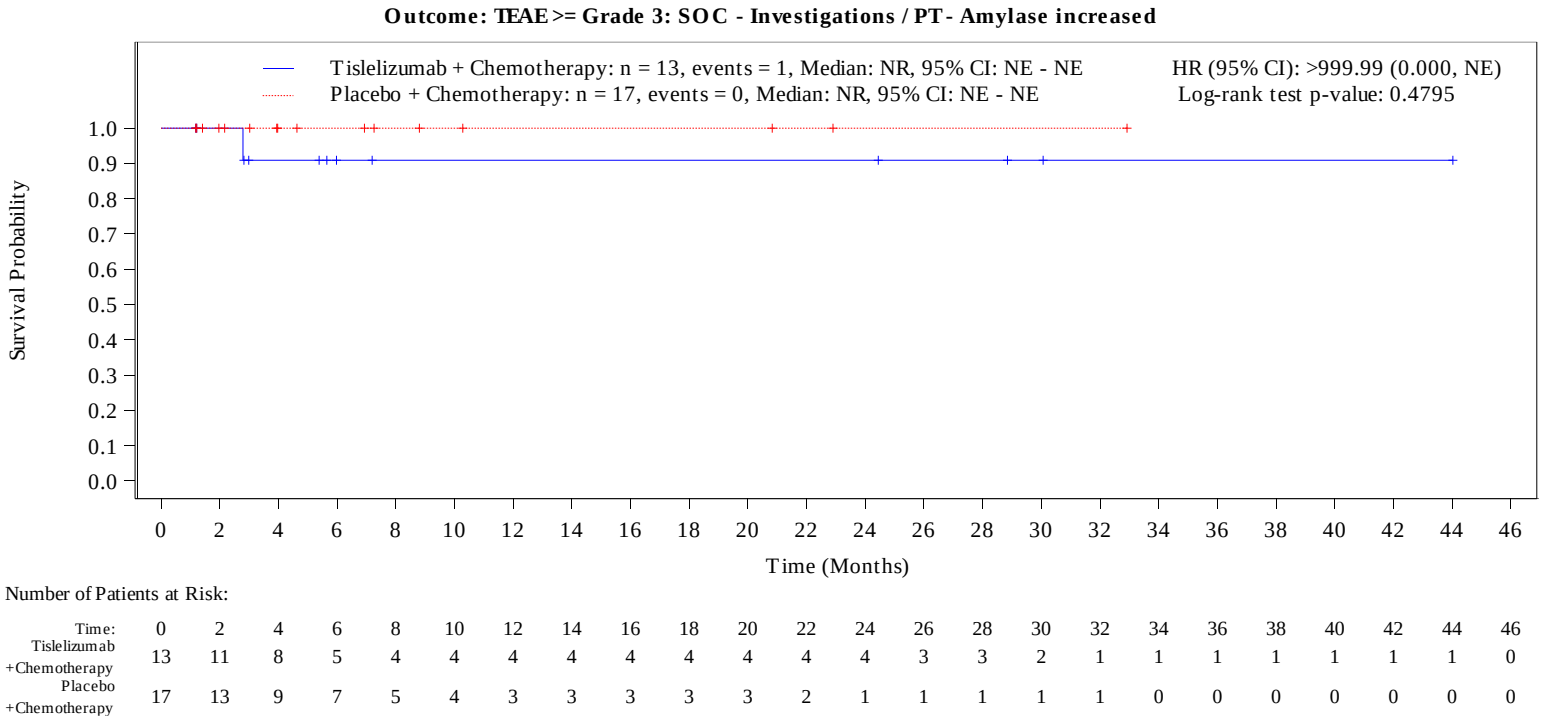

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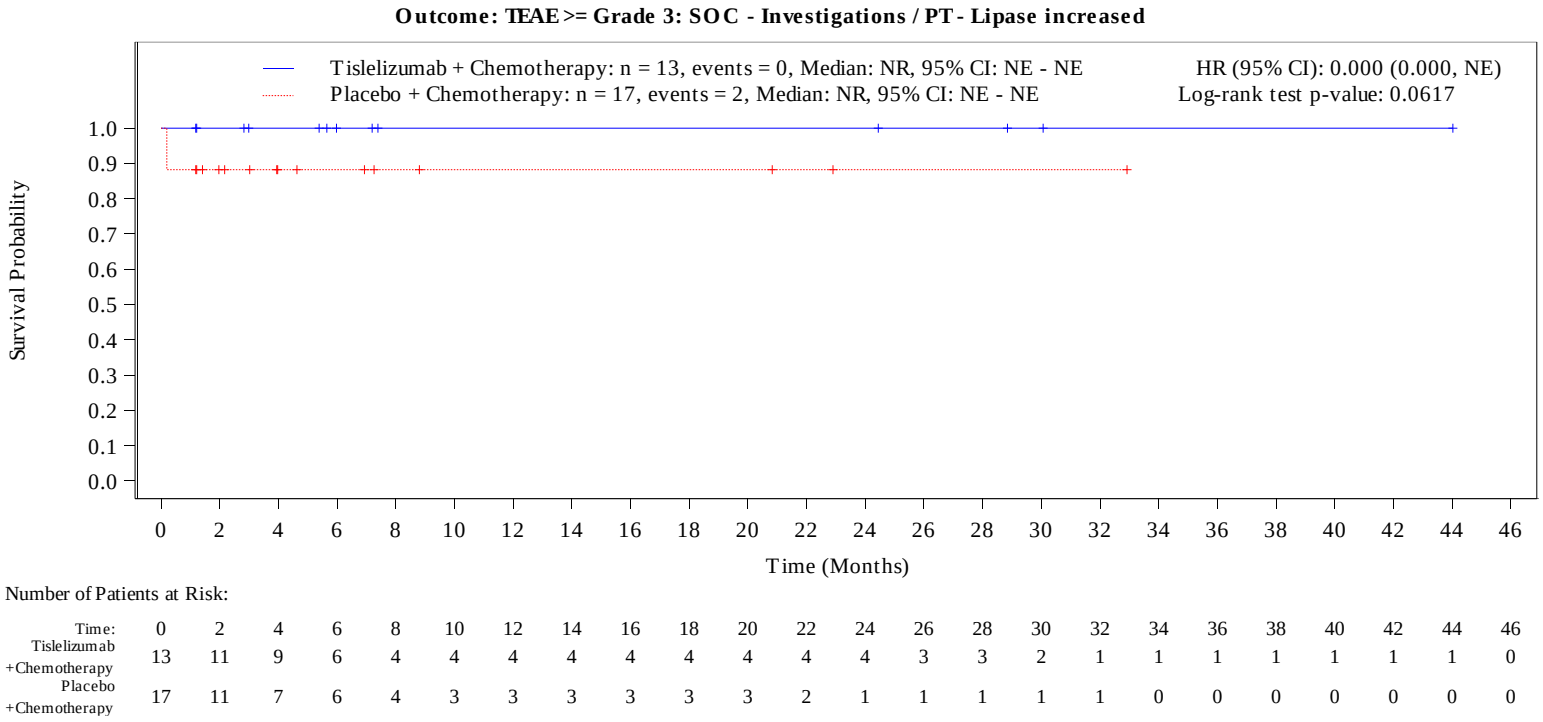

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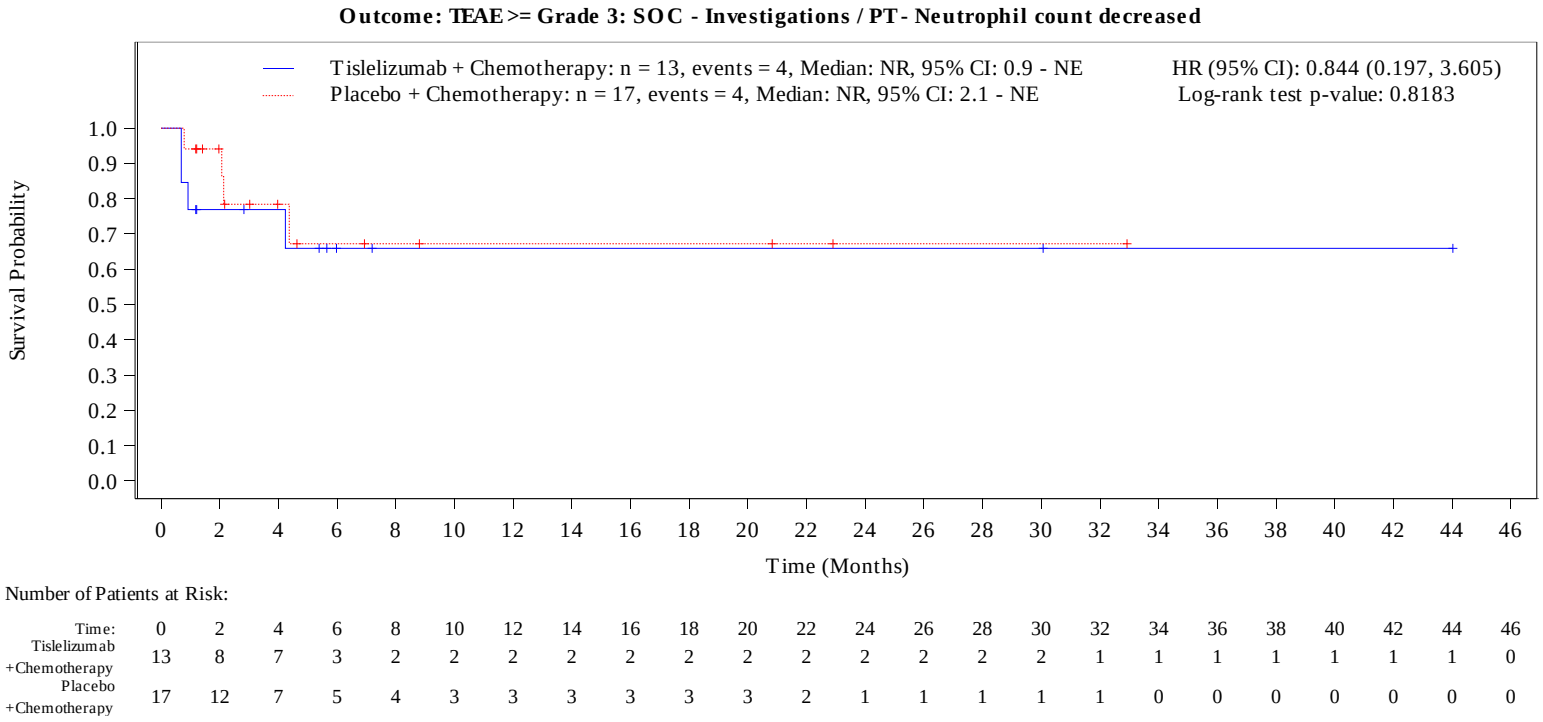

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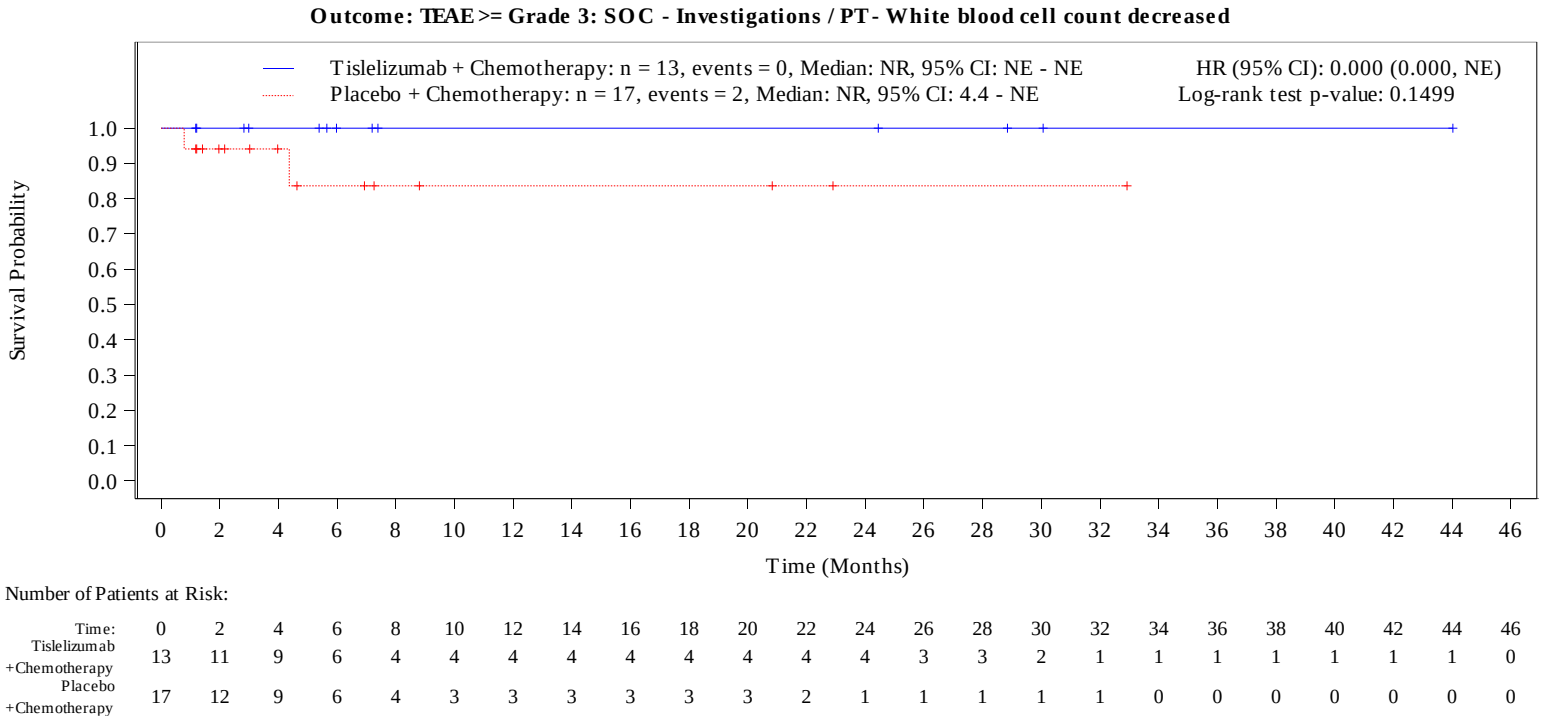

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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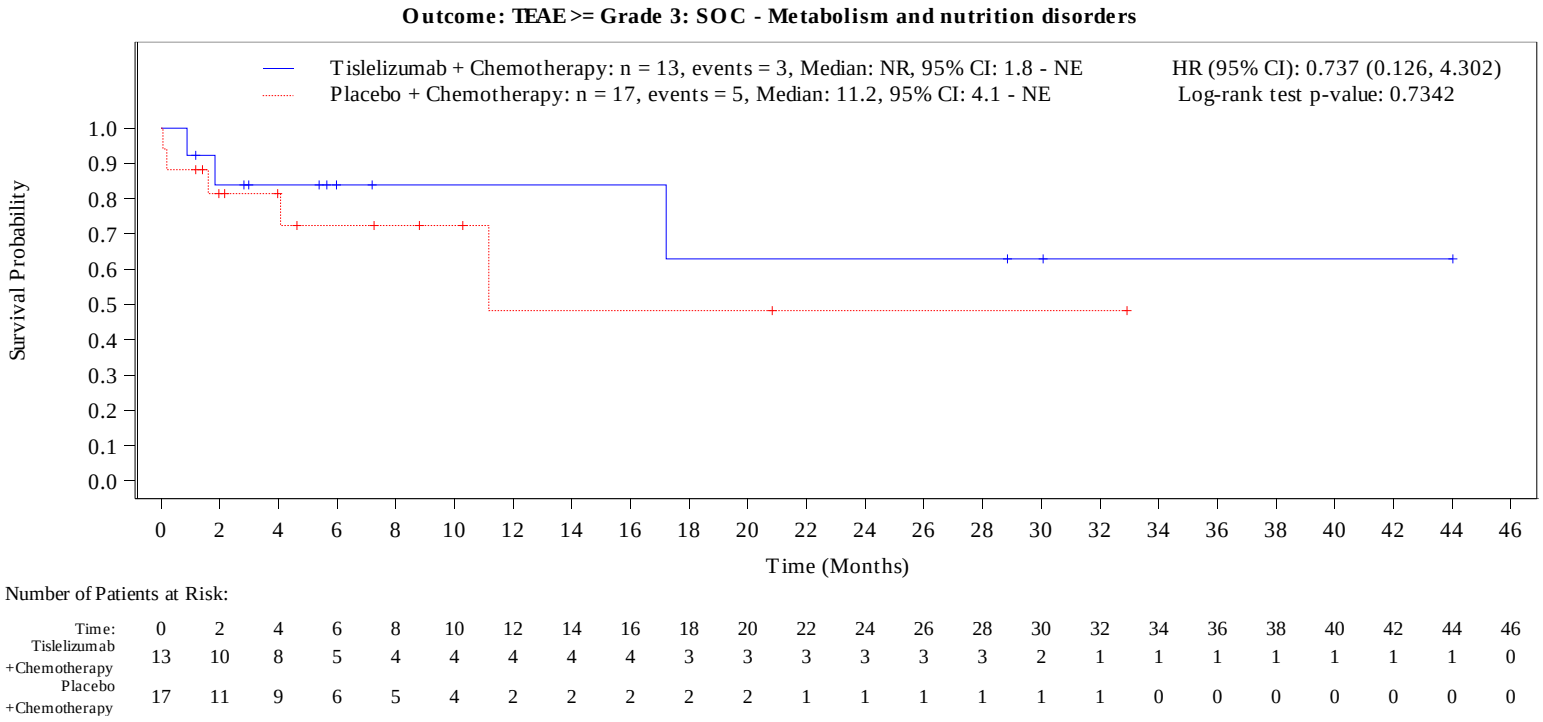
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

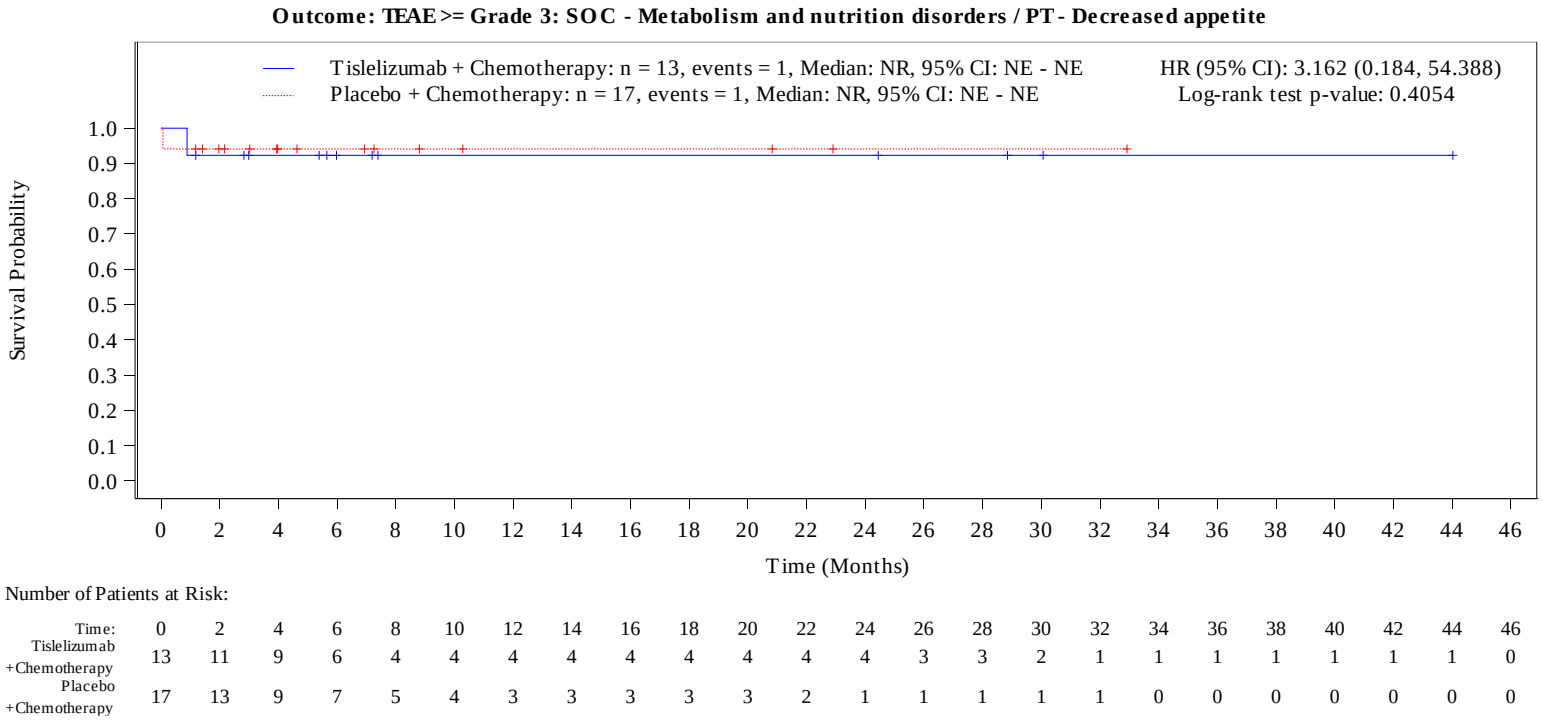

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Figure 14.3.1.3:
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Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

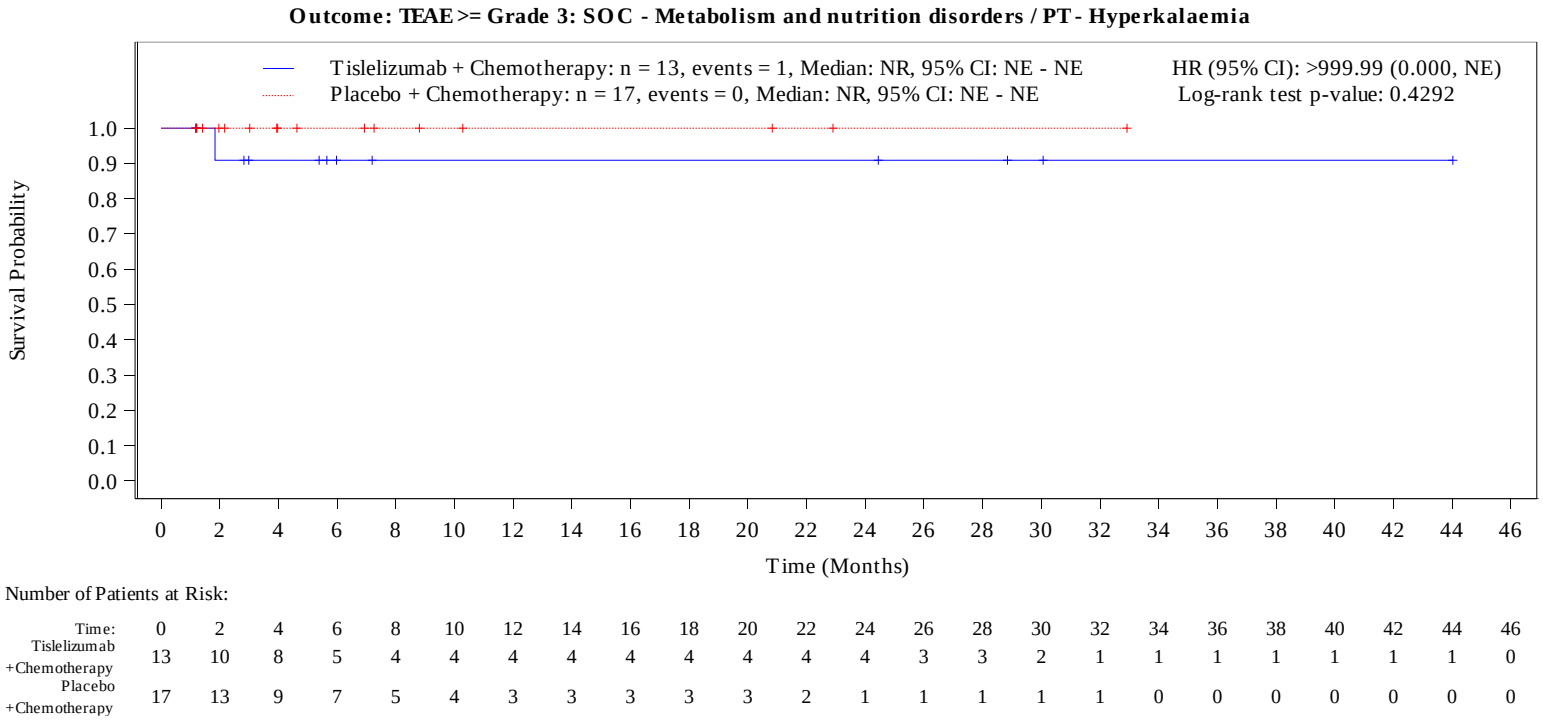

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Figure 14.3.1.3:
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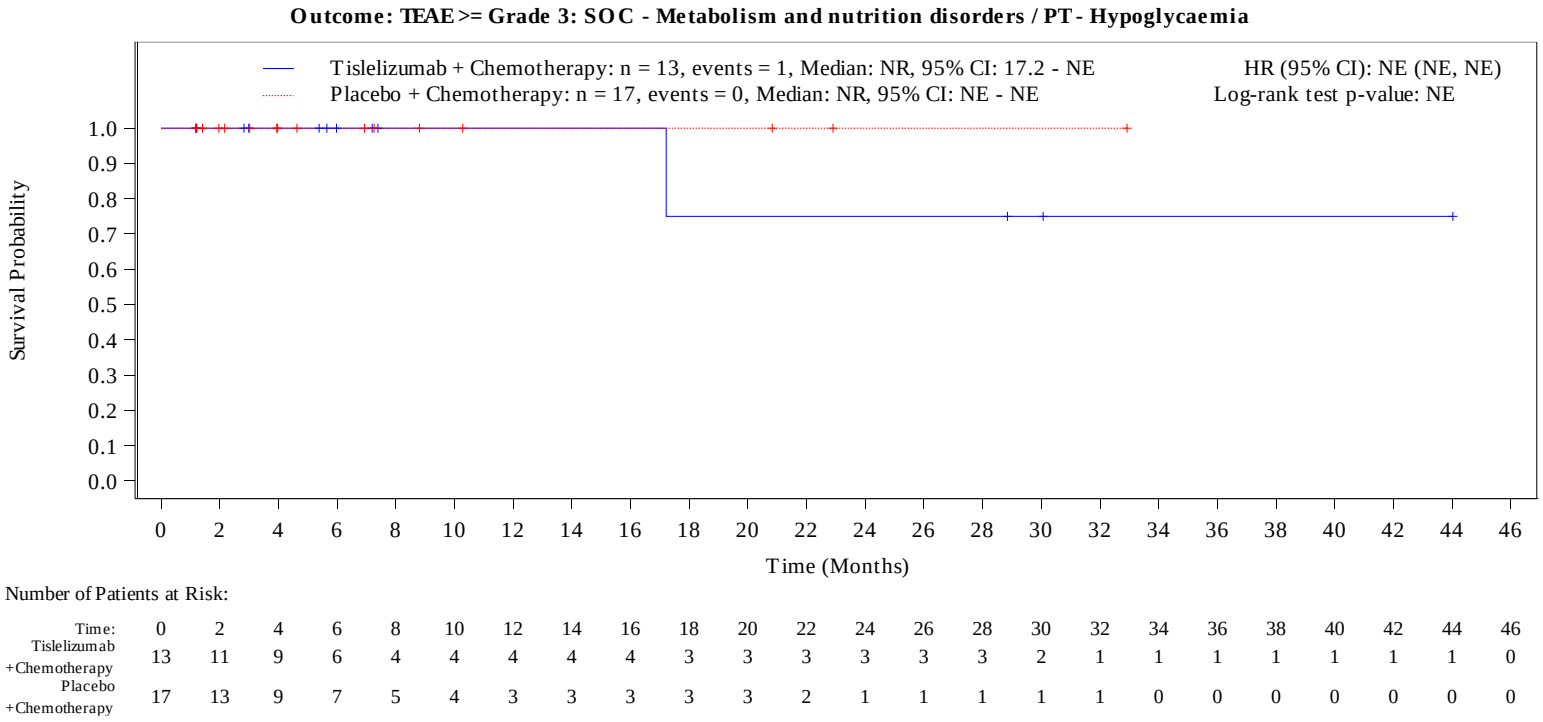

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
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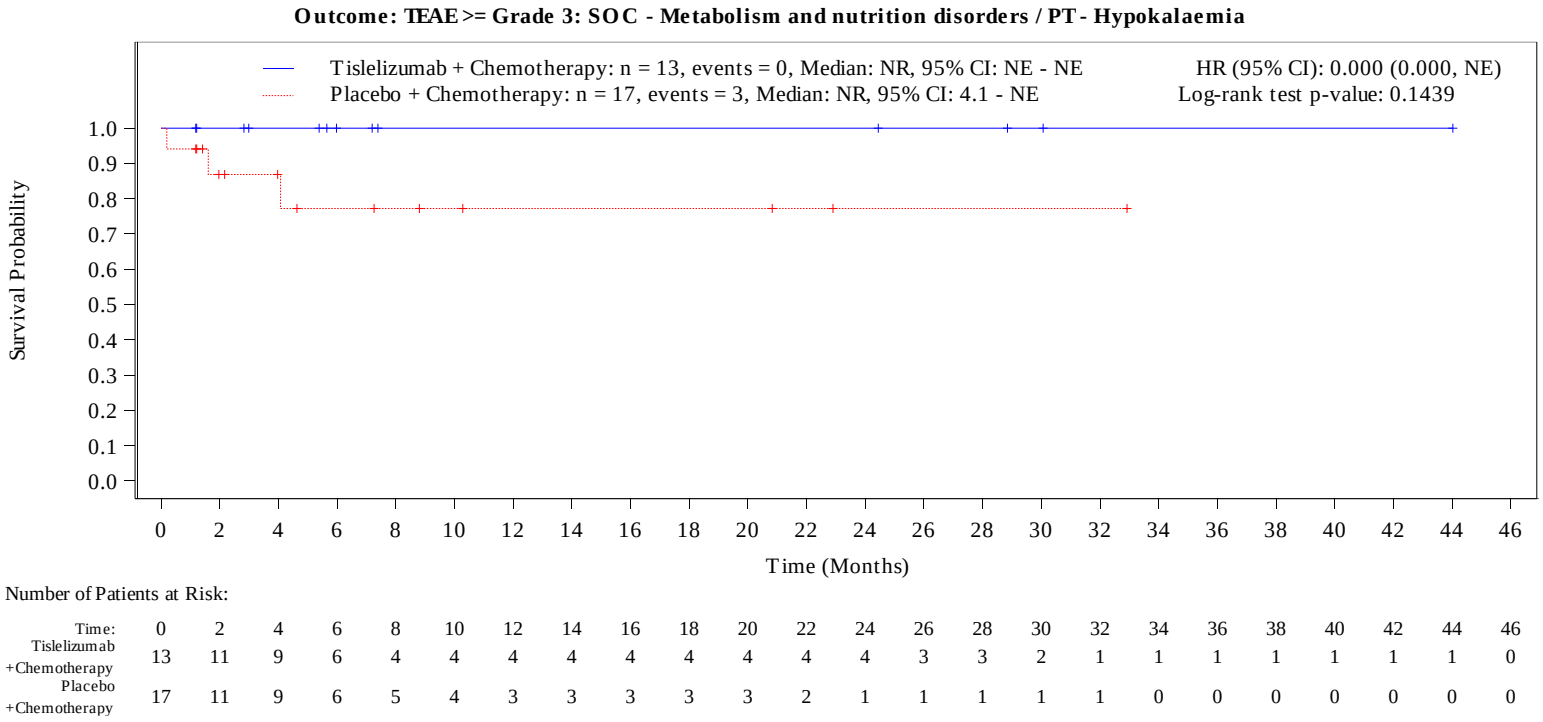

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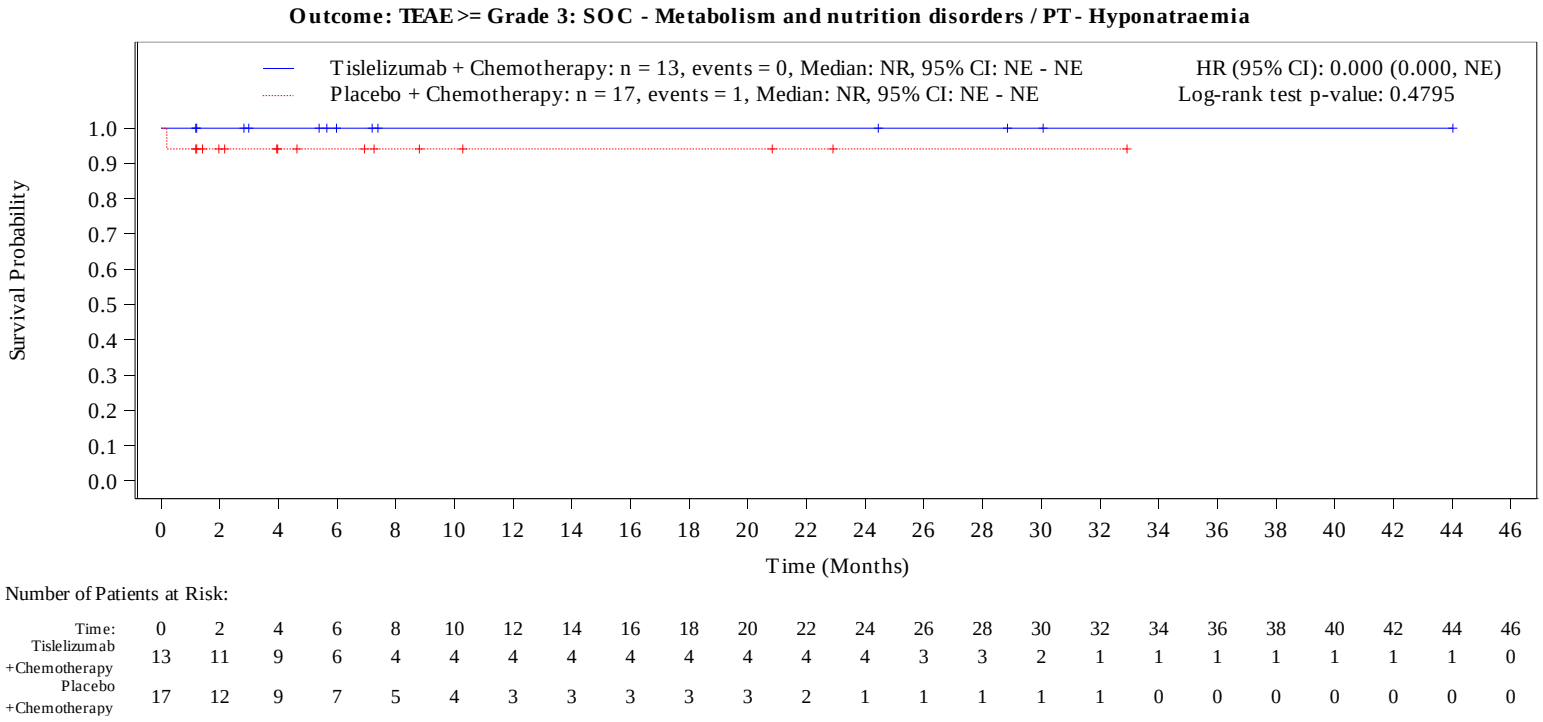

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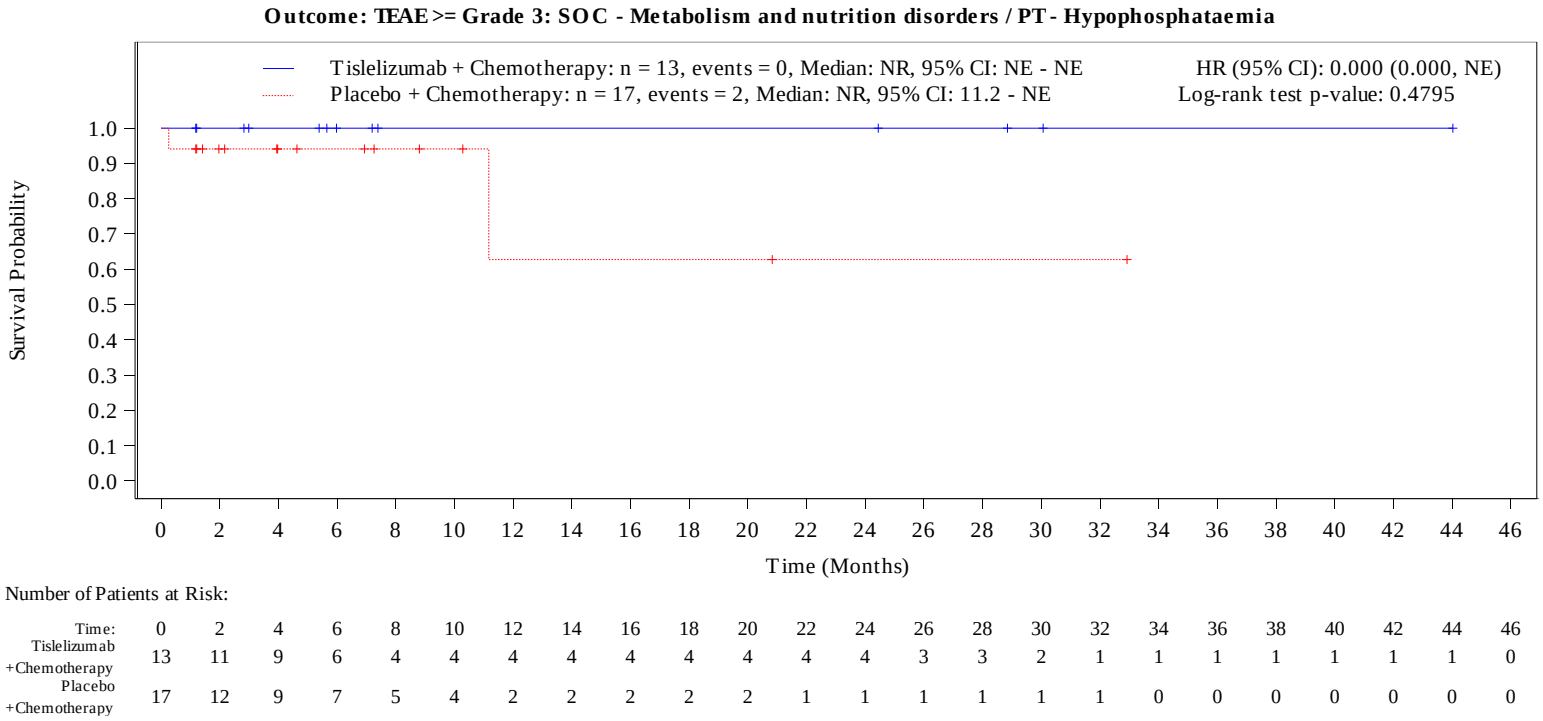

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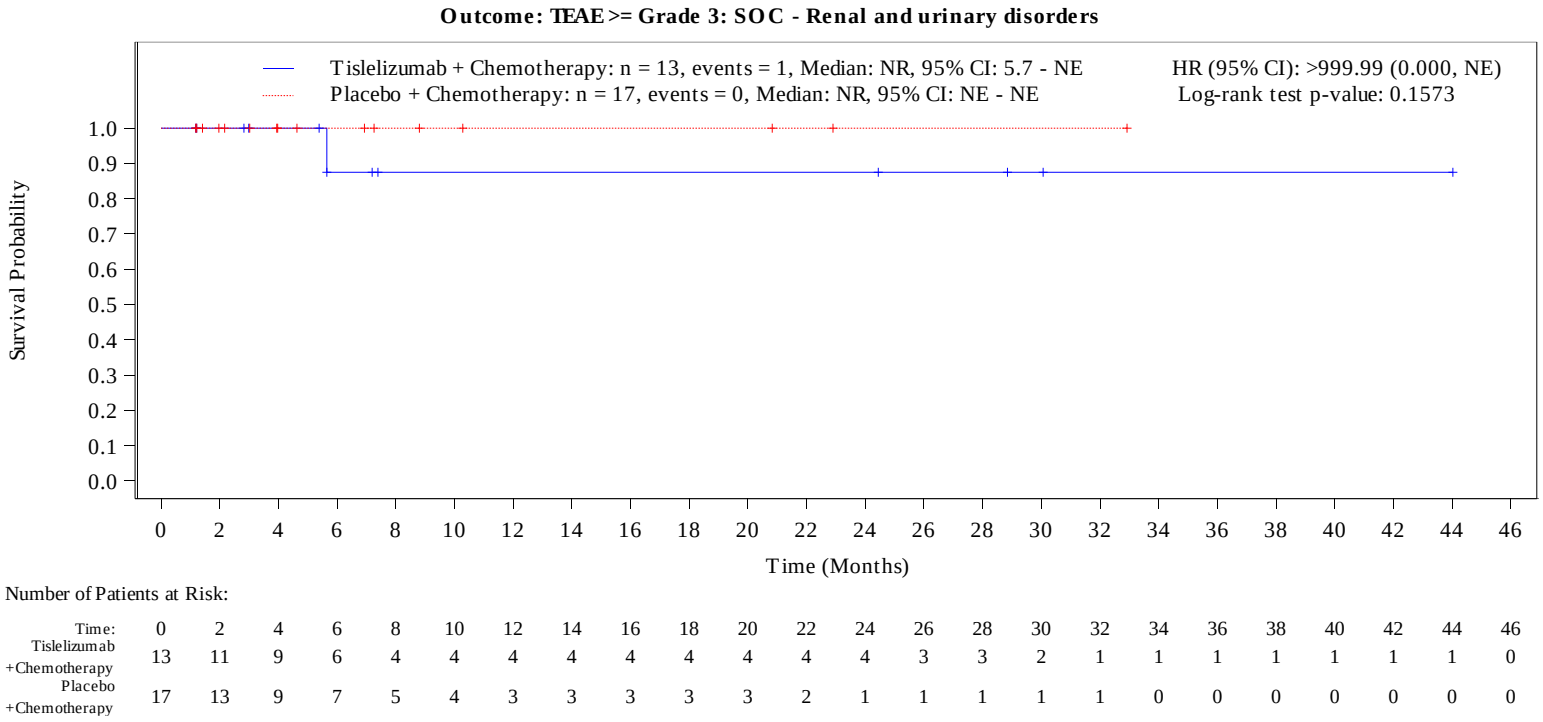

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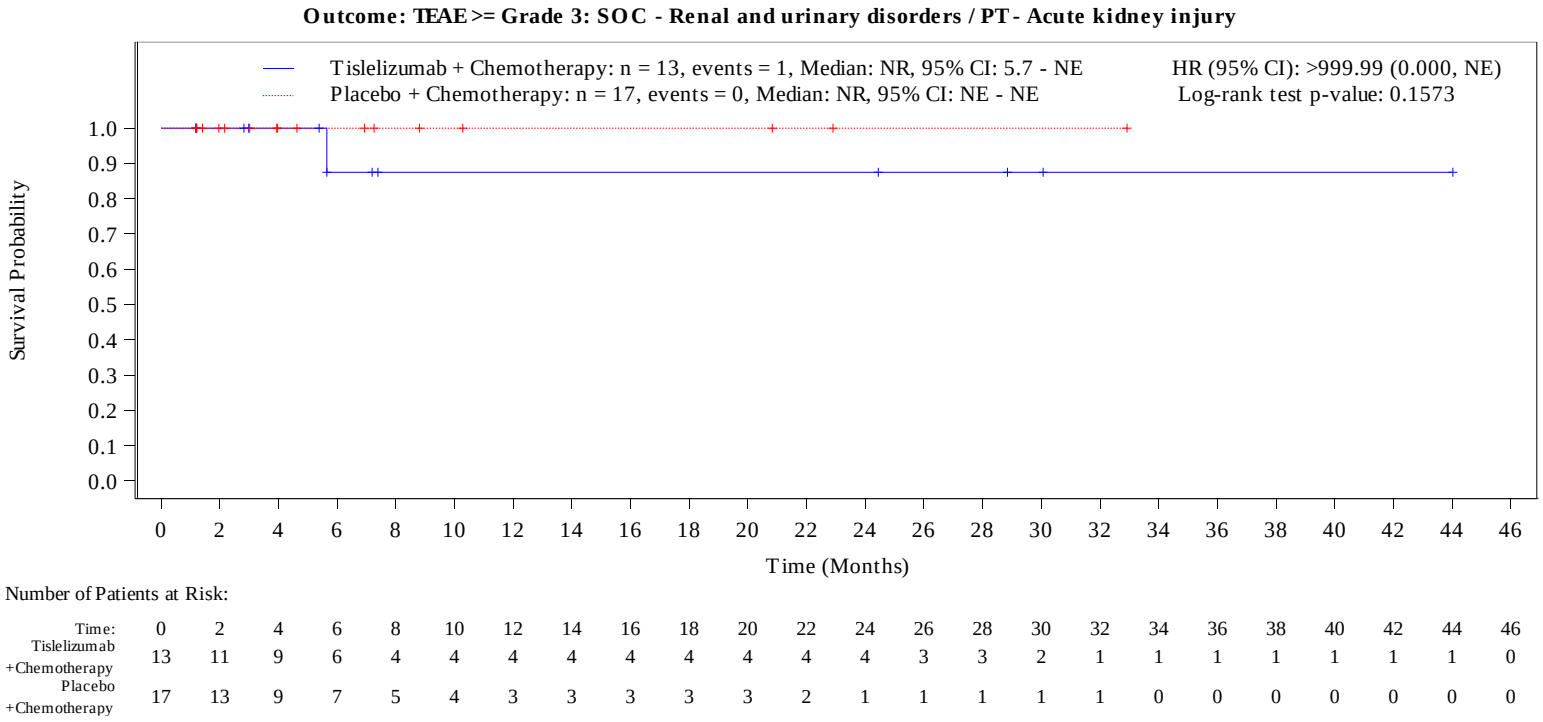

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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
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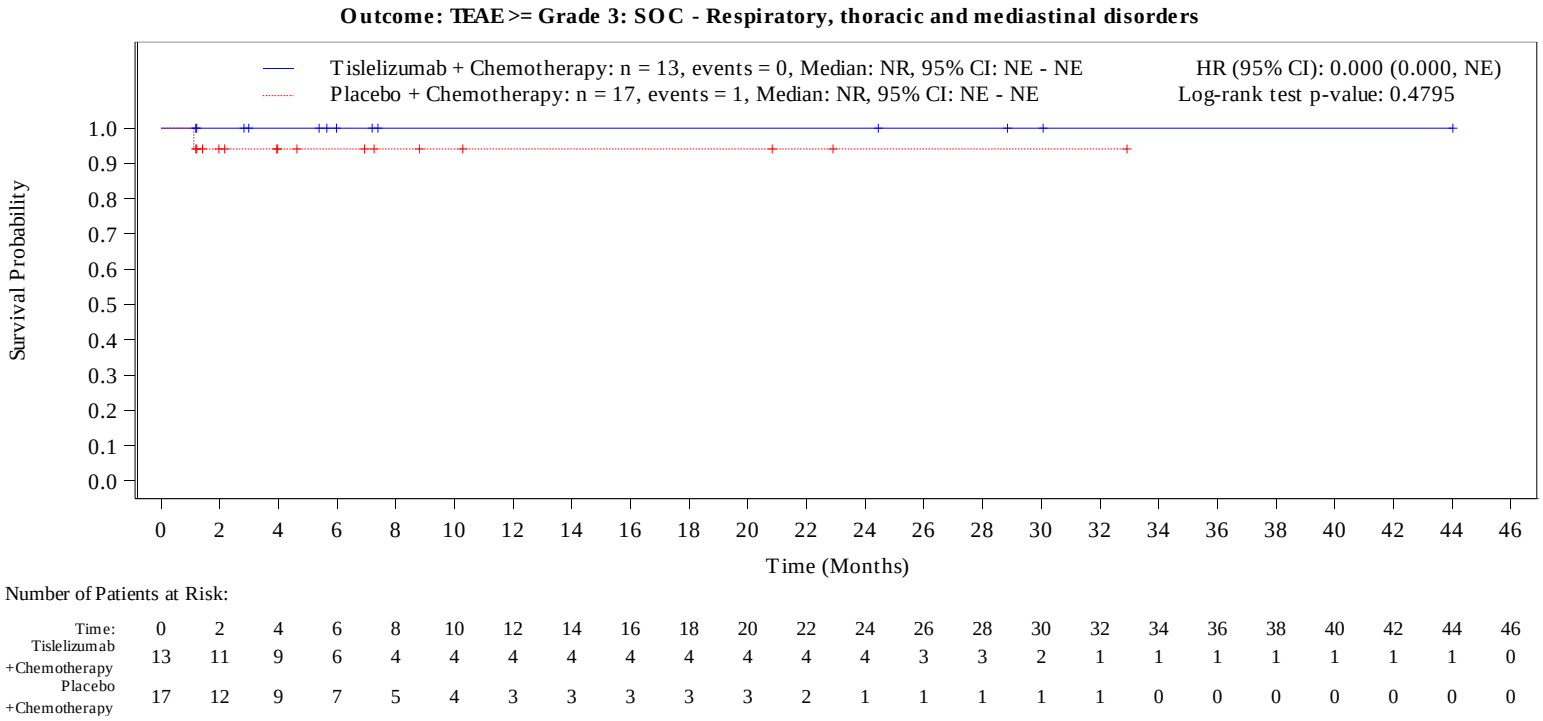

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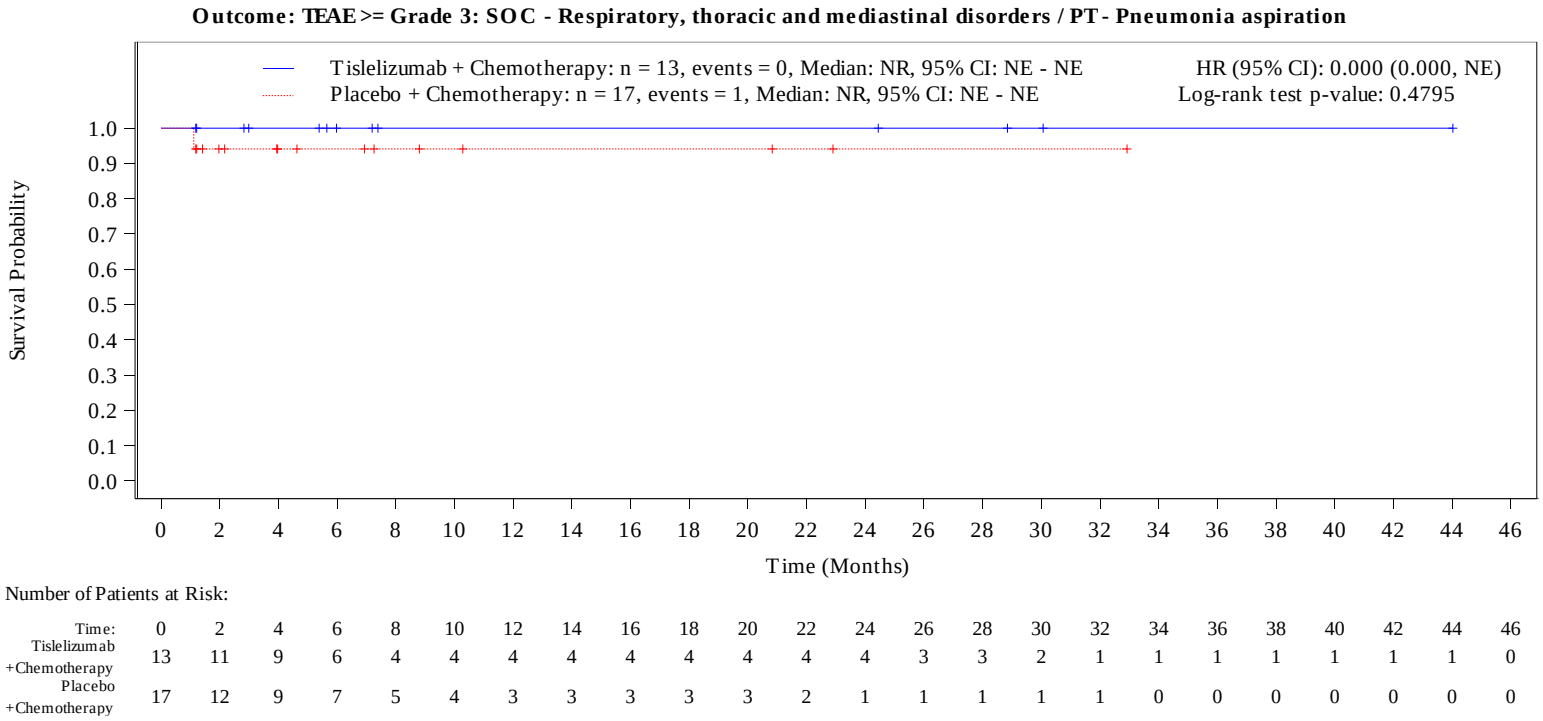

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

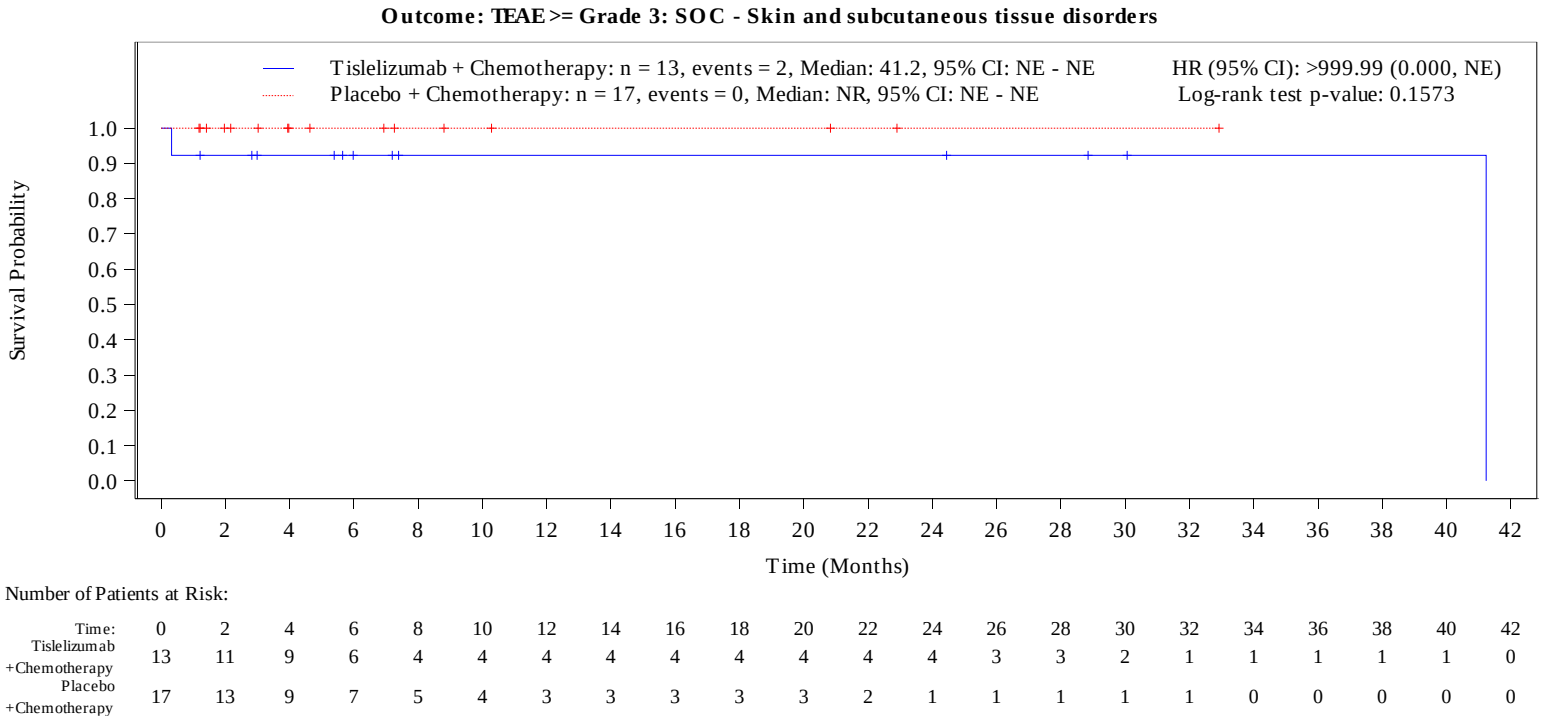

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

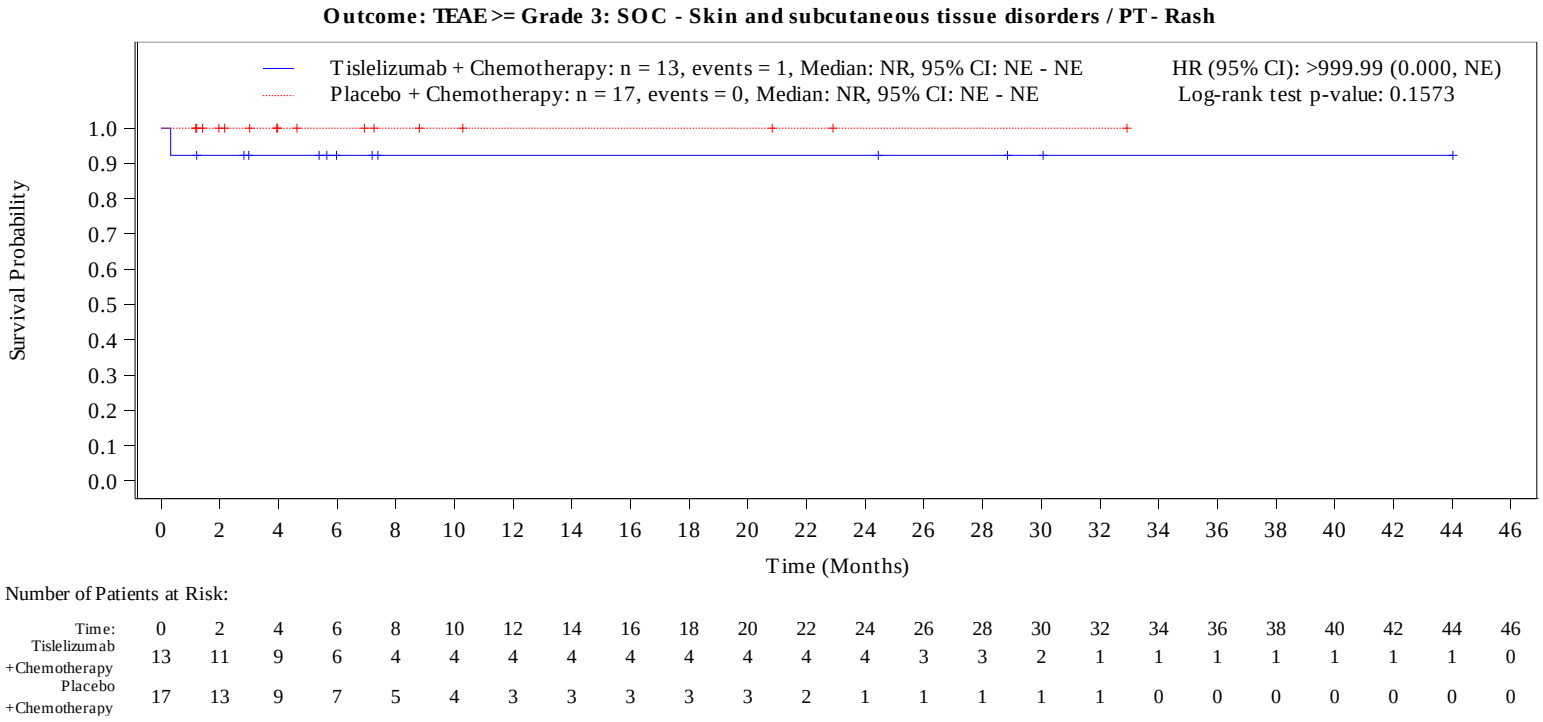

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

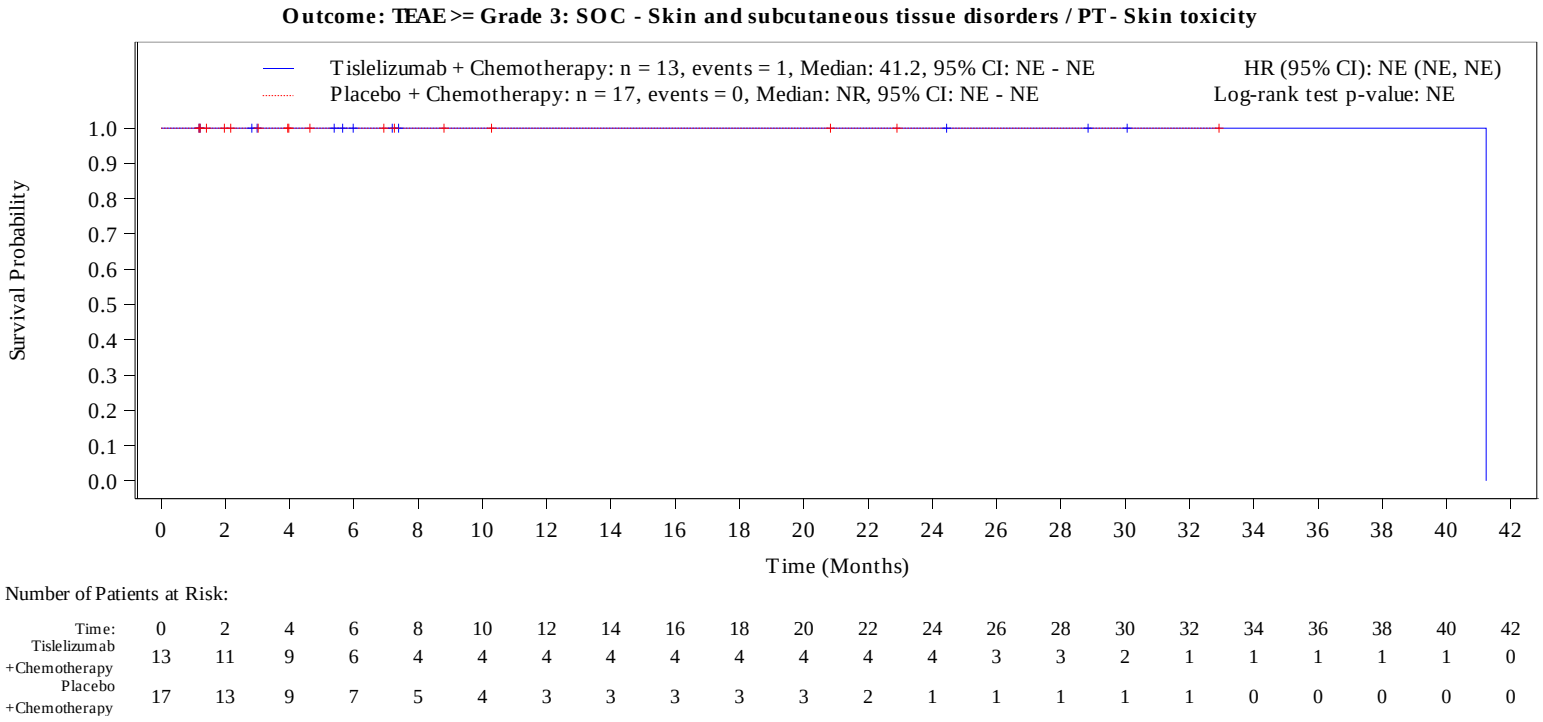

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

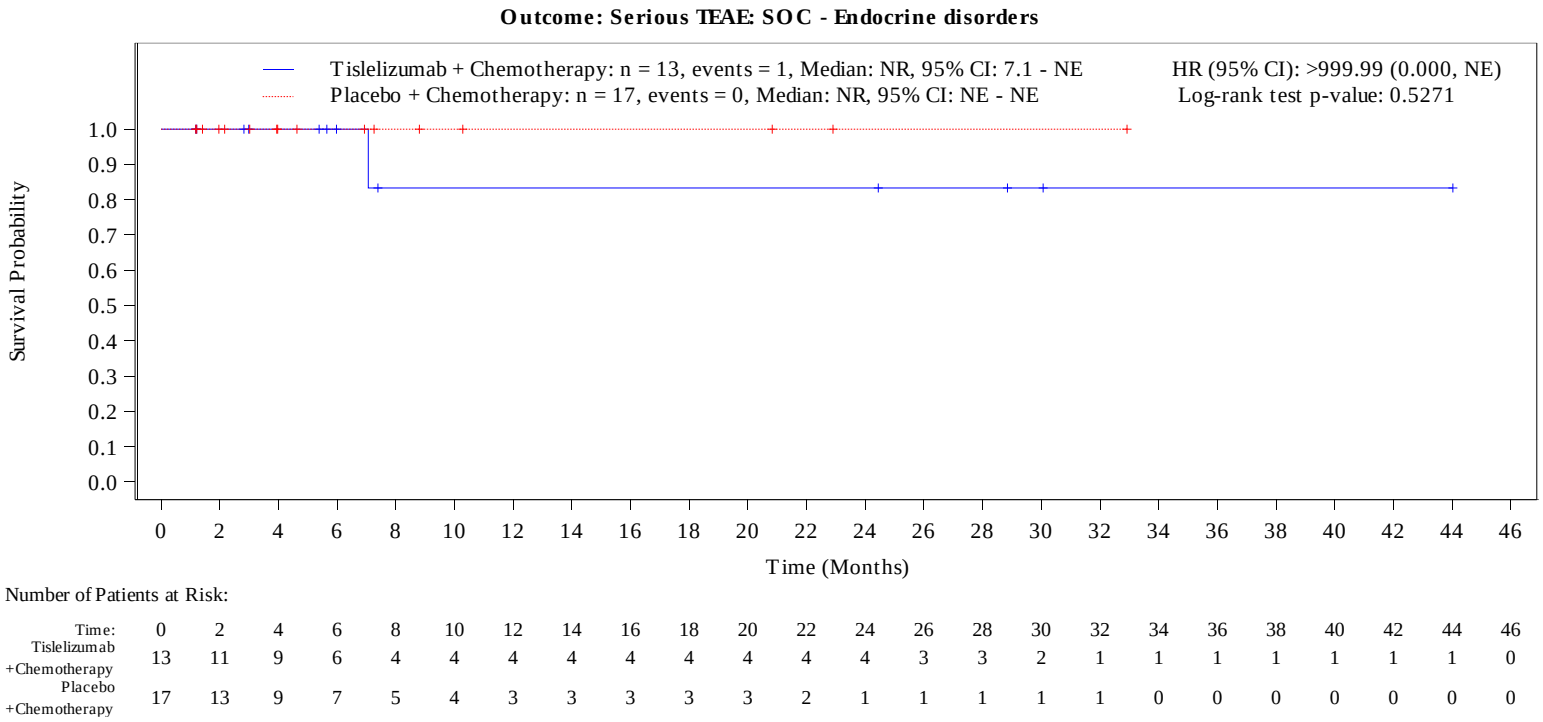

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

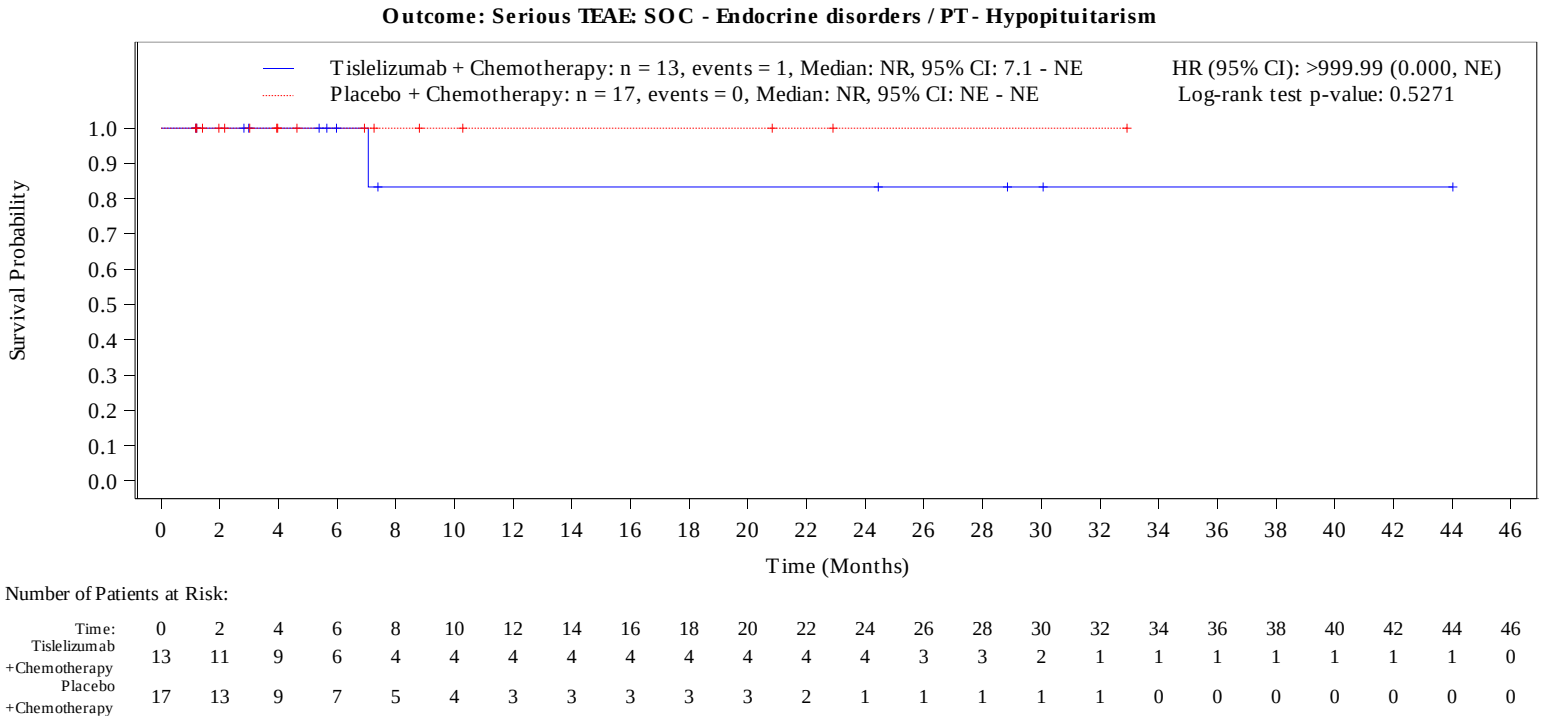

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

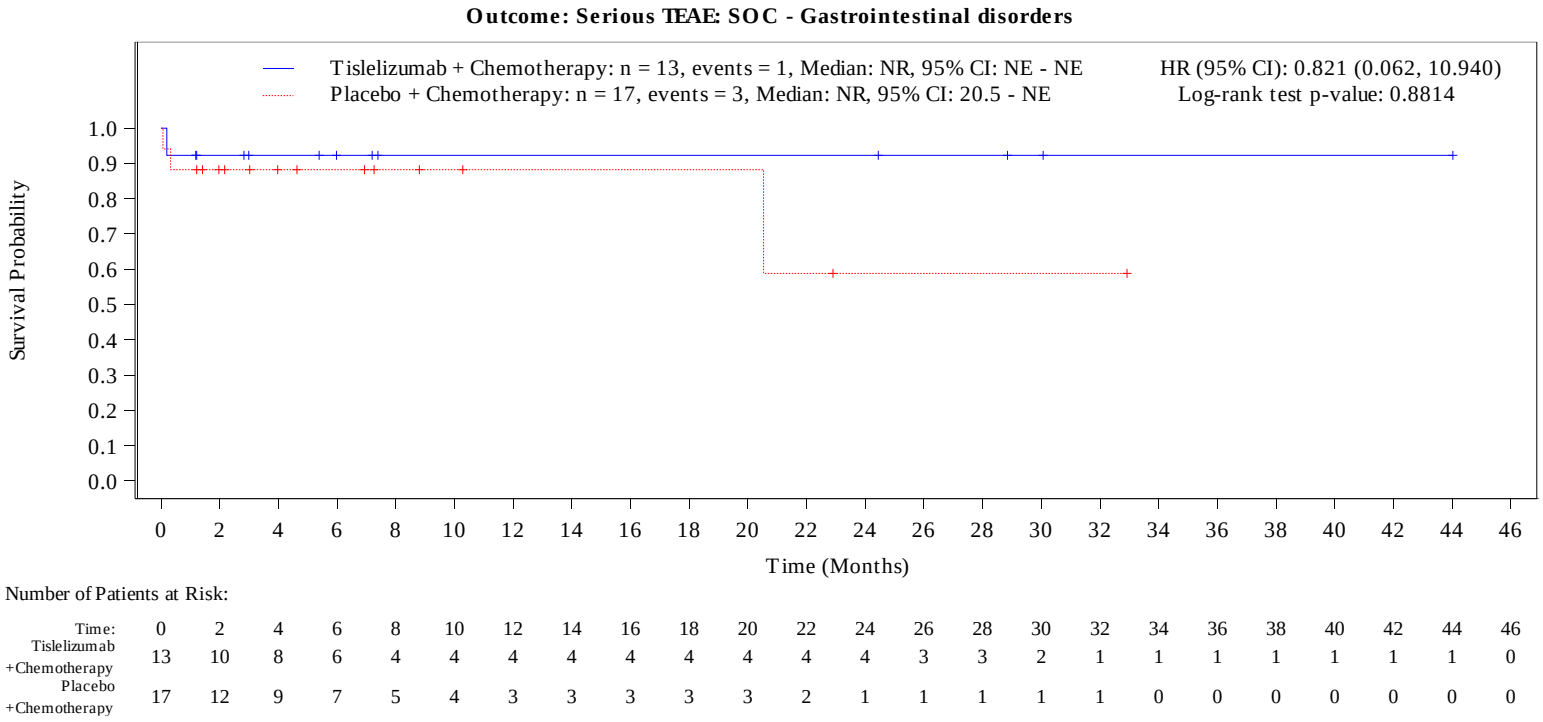

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

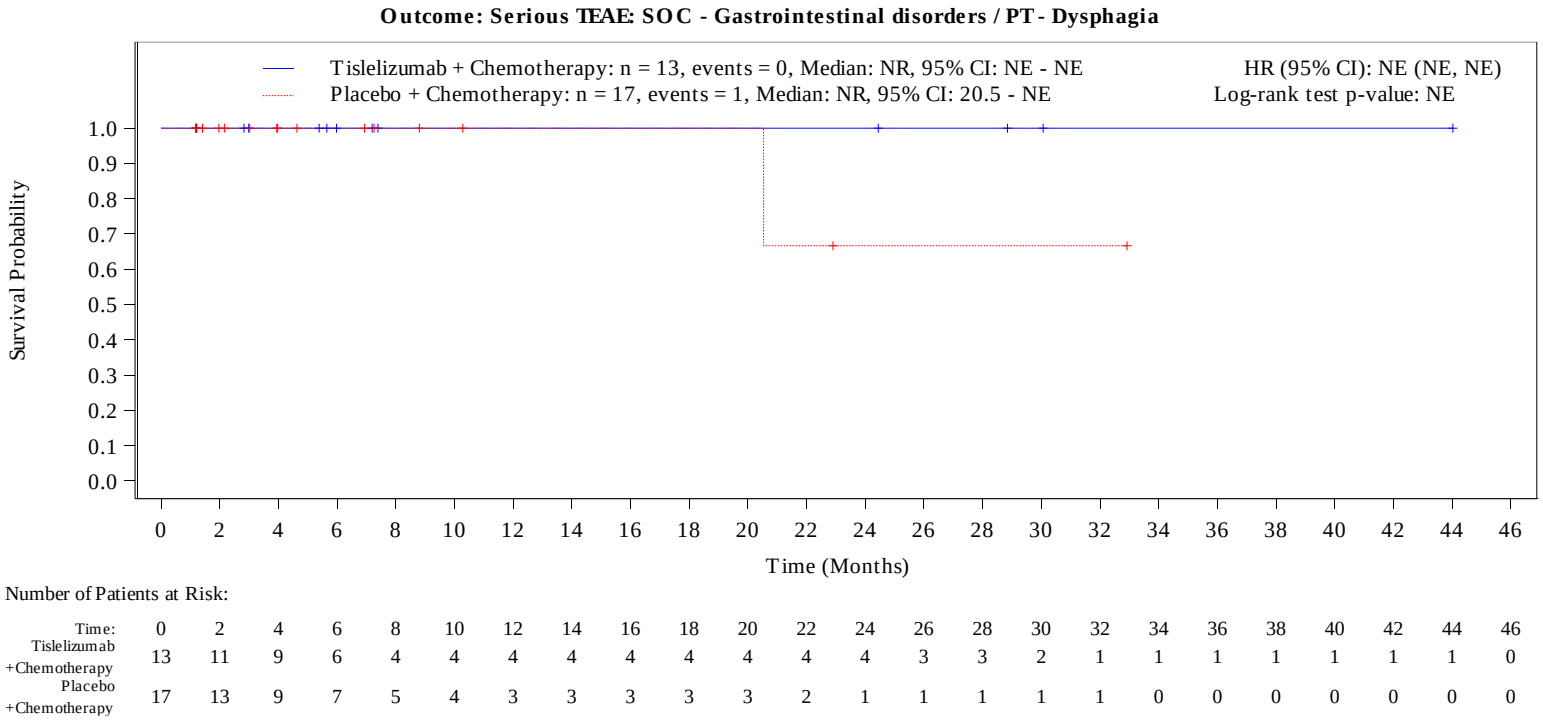

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Figure 14.3.1.4:
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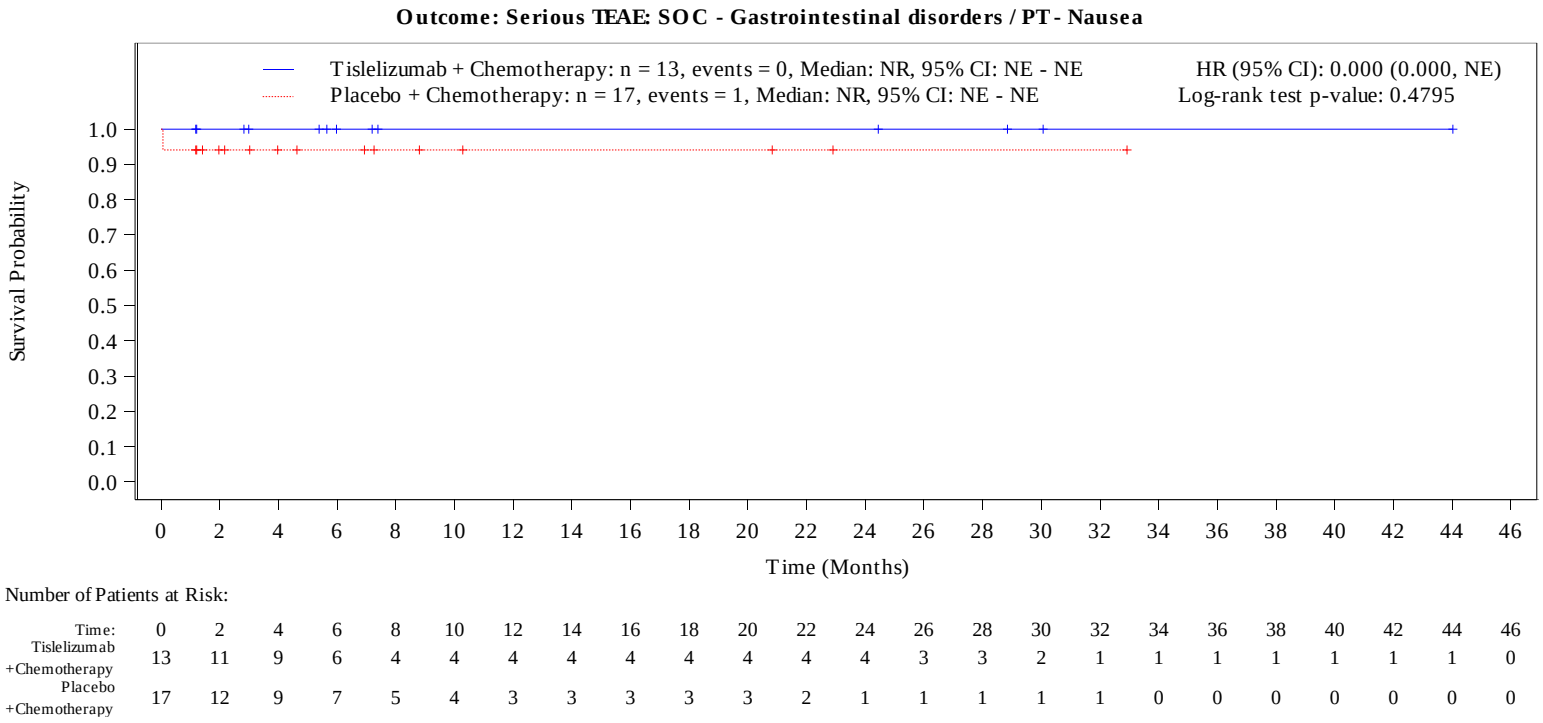

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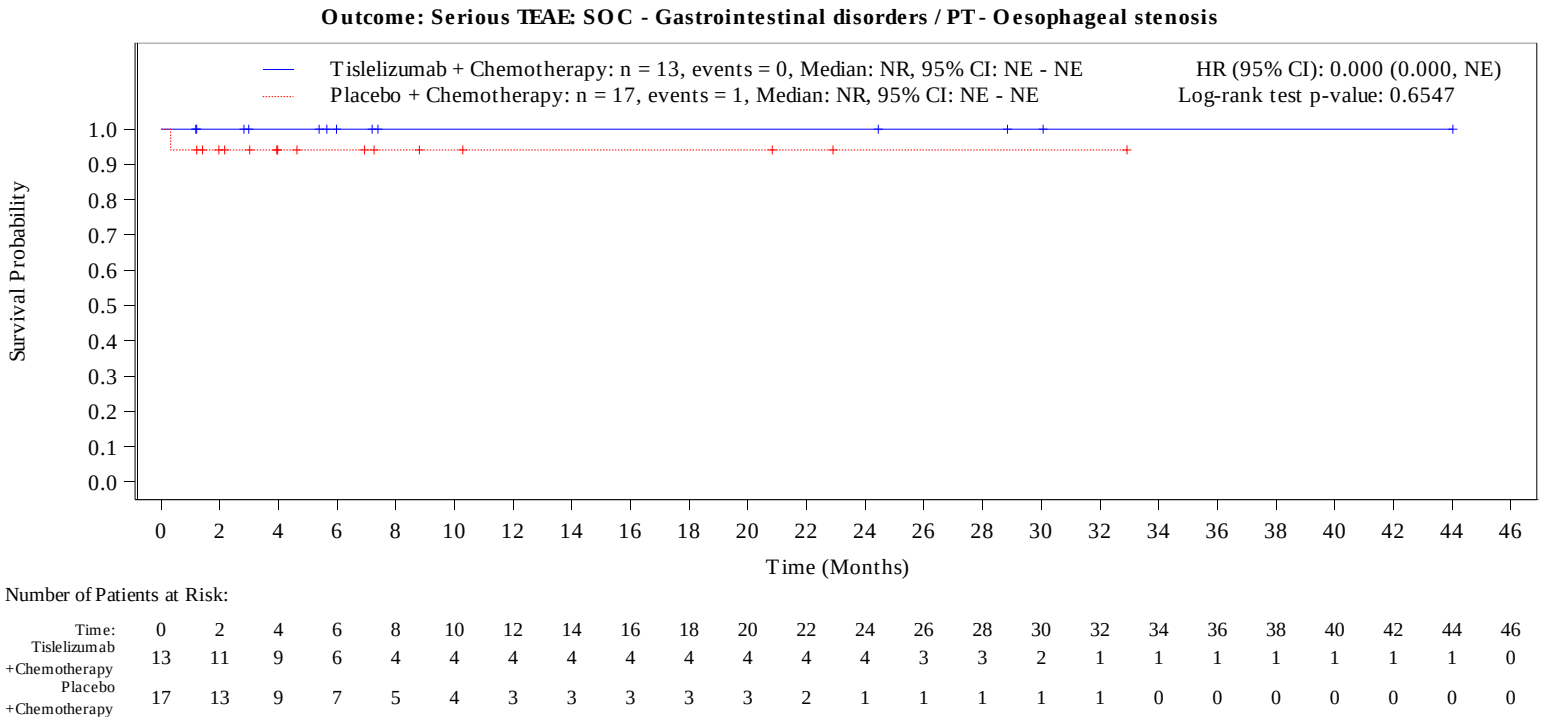
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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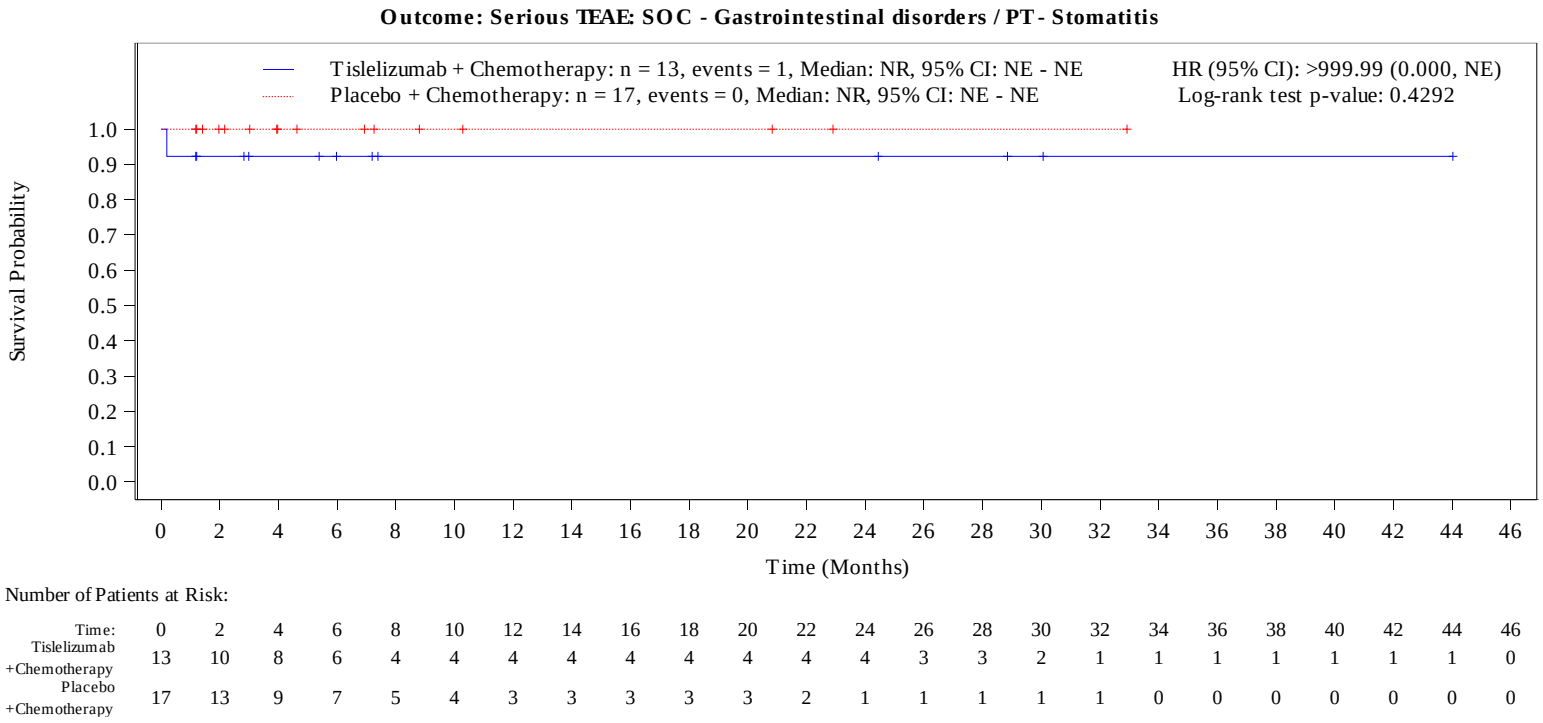

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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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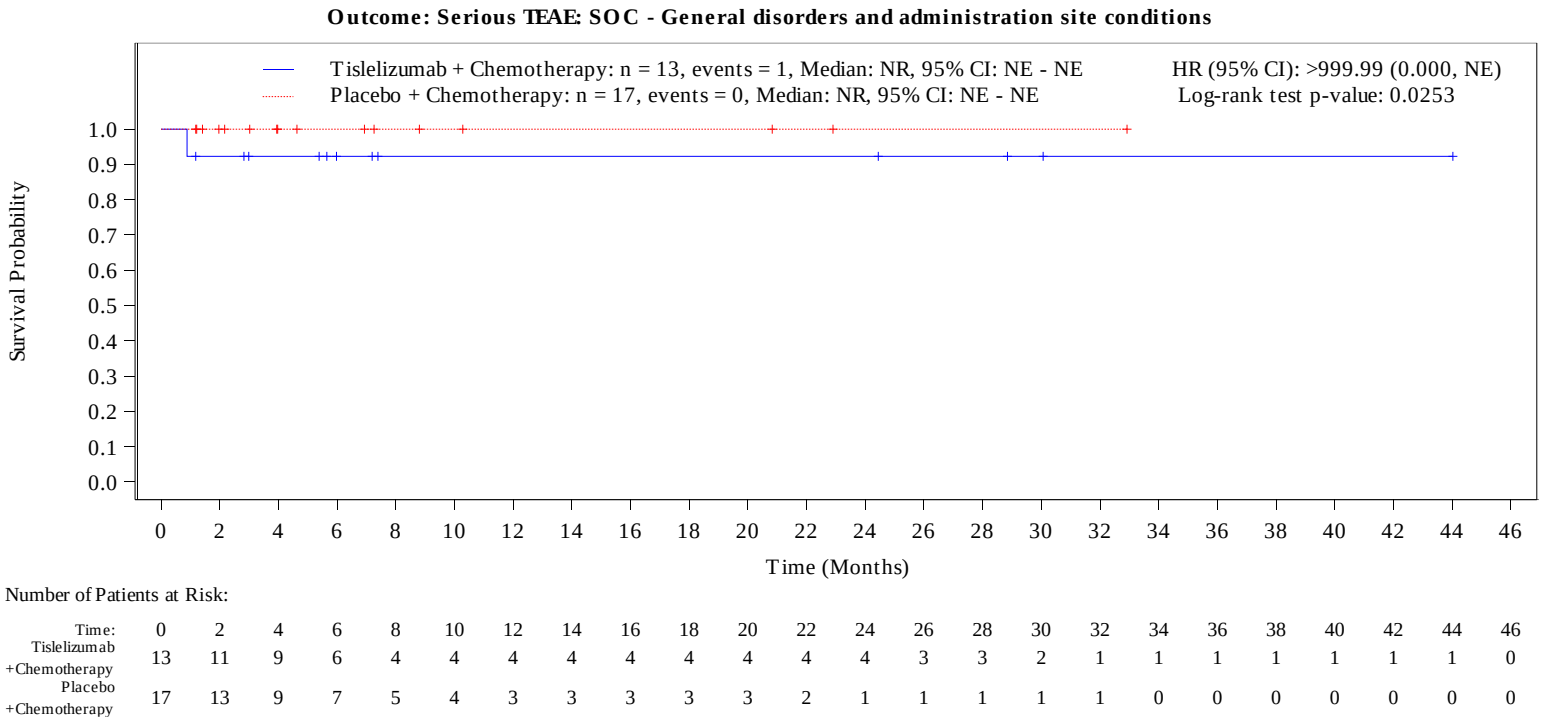

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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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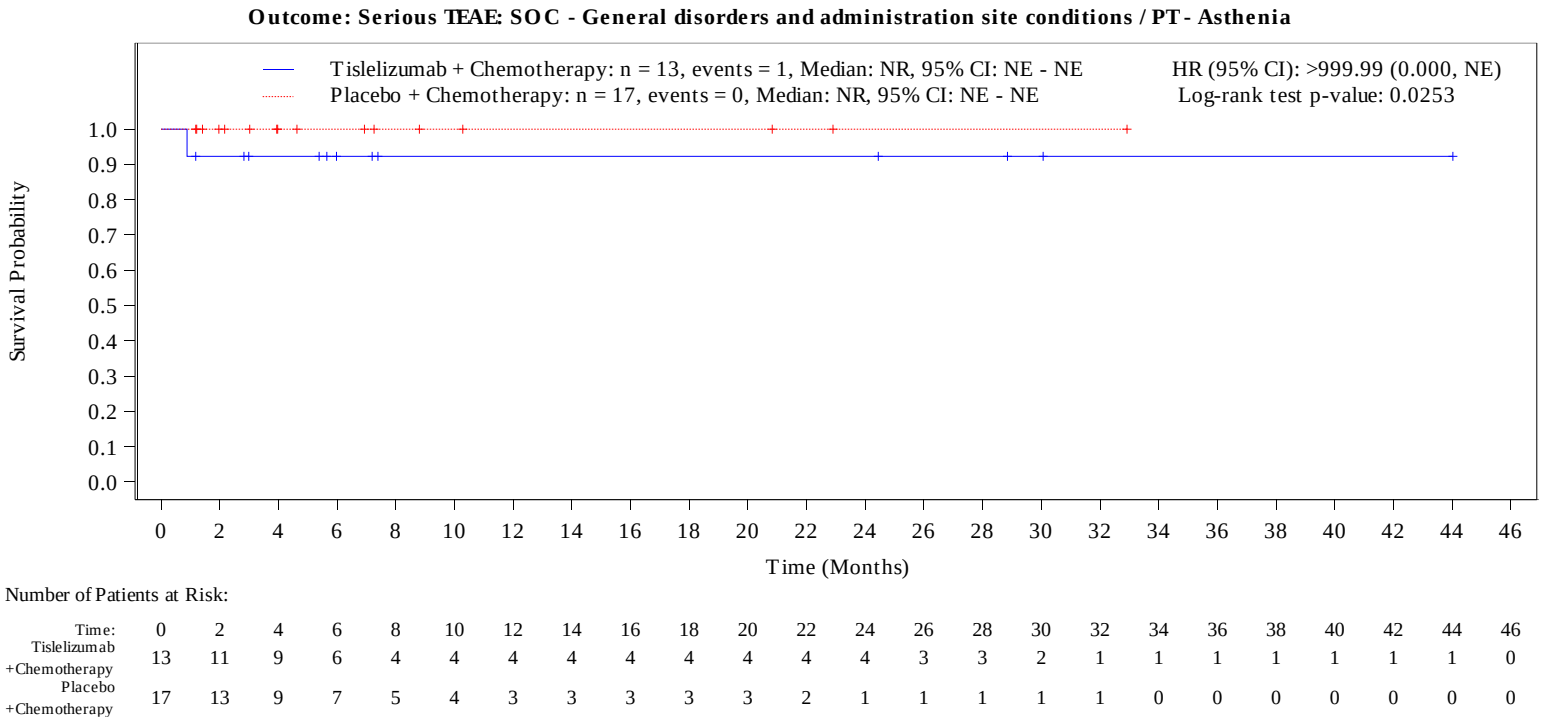

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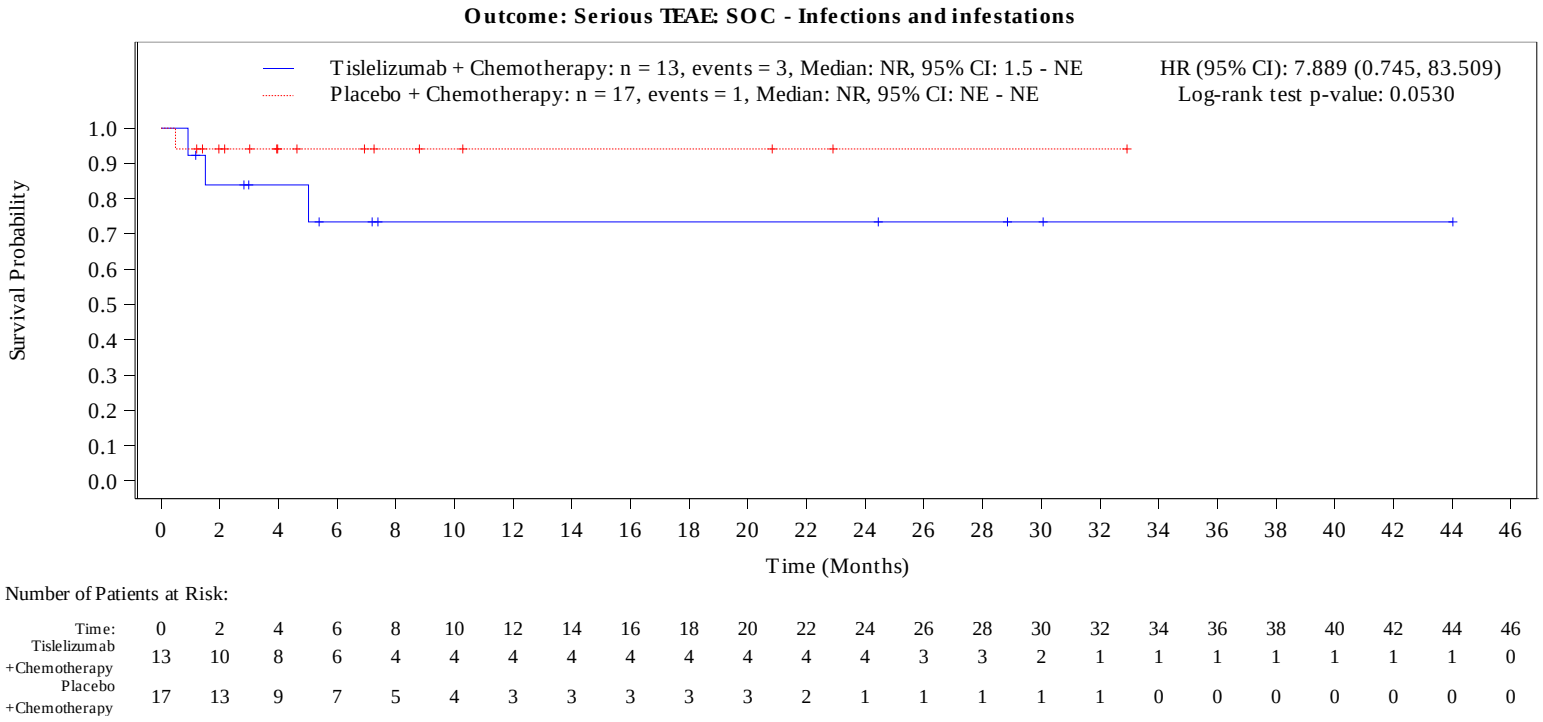

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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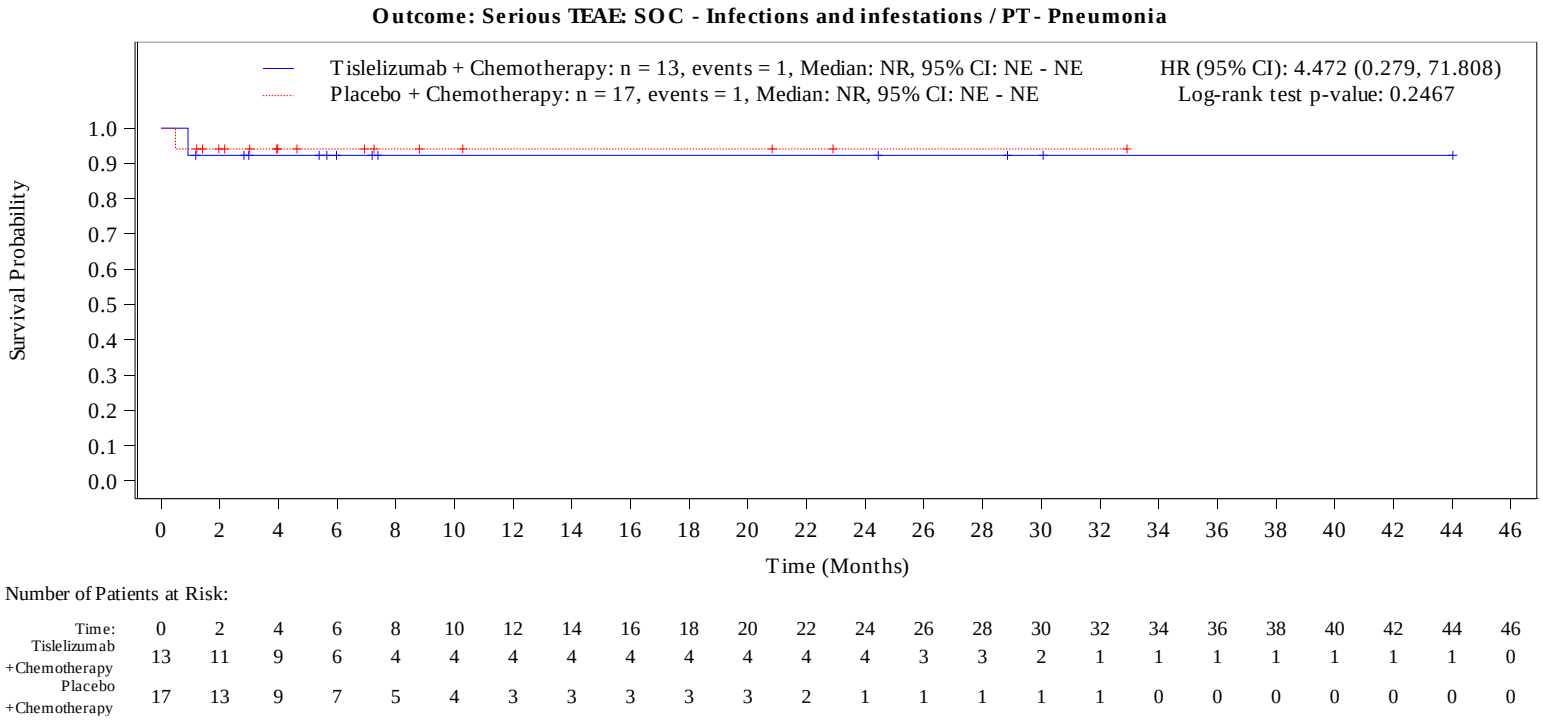

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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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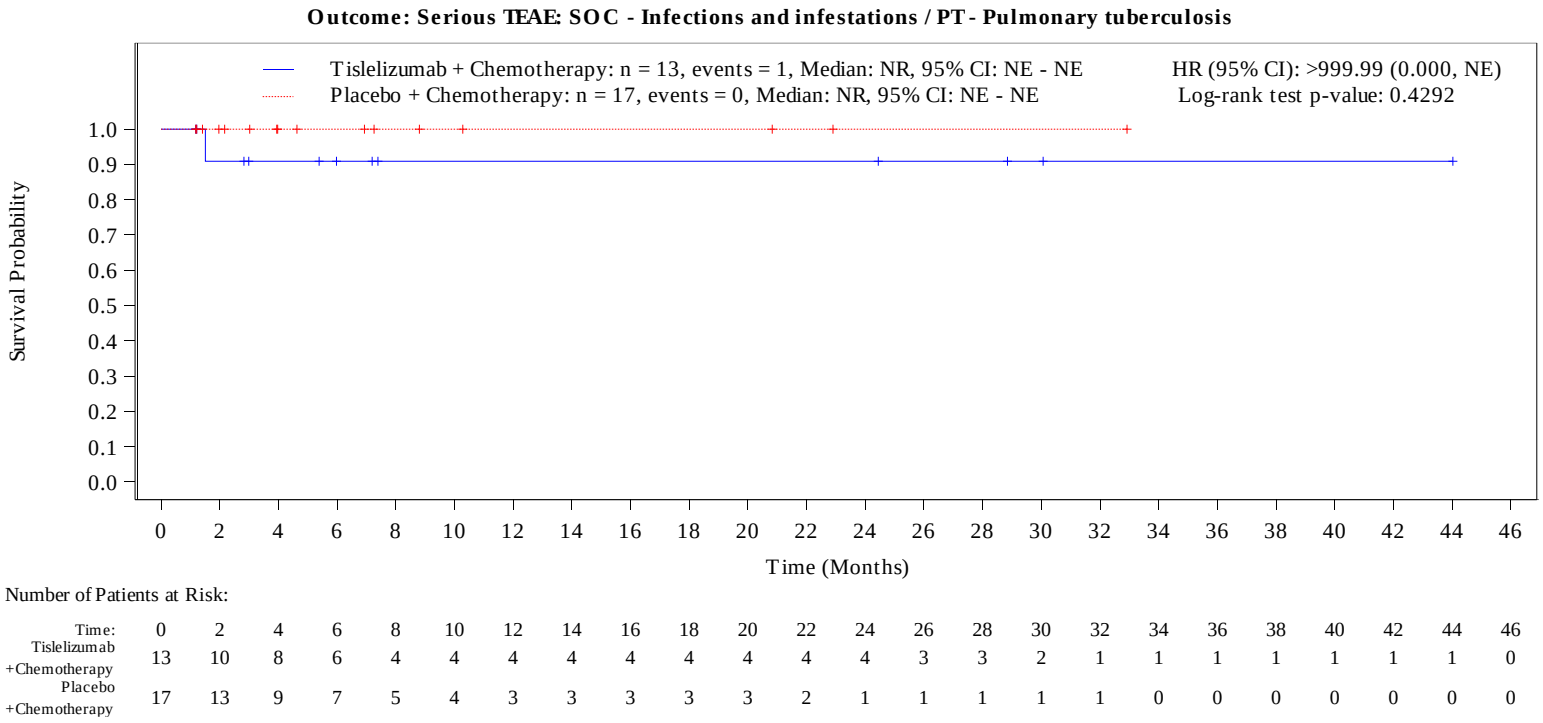
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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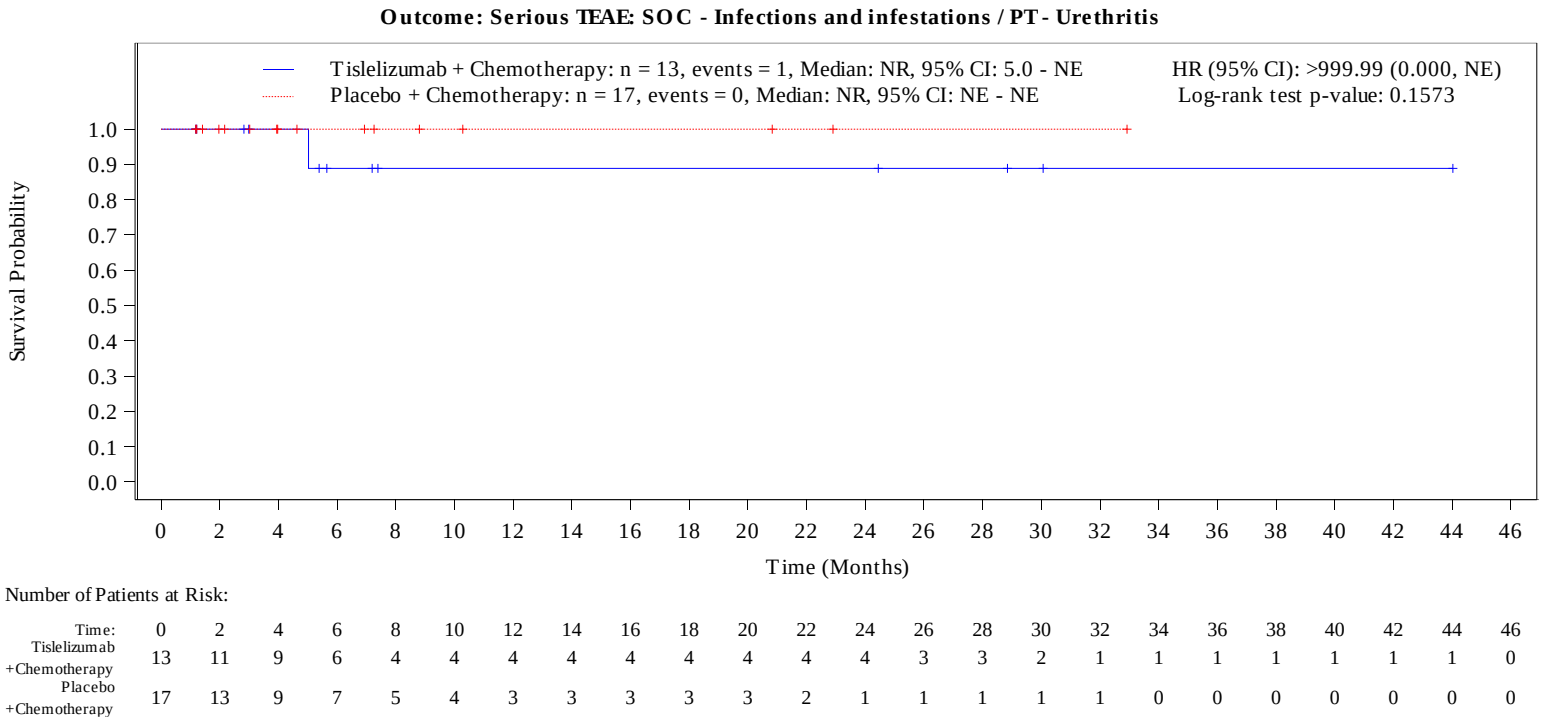
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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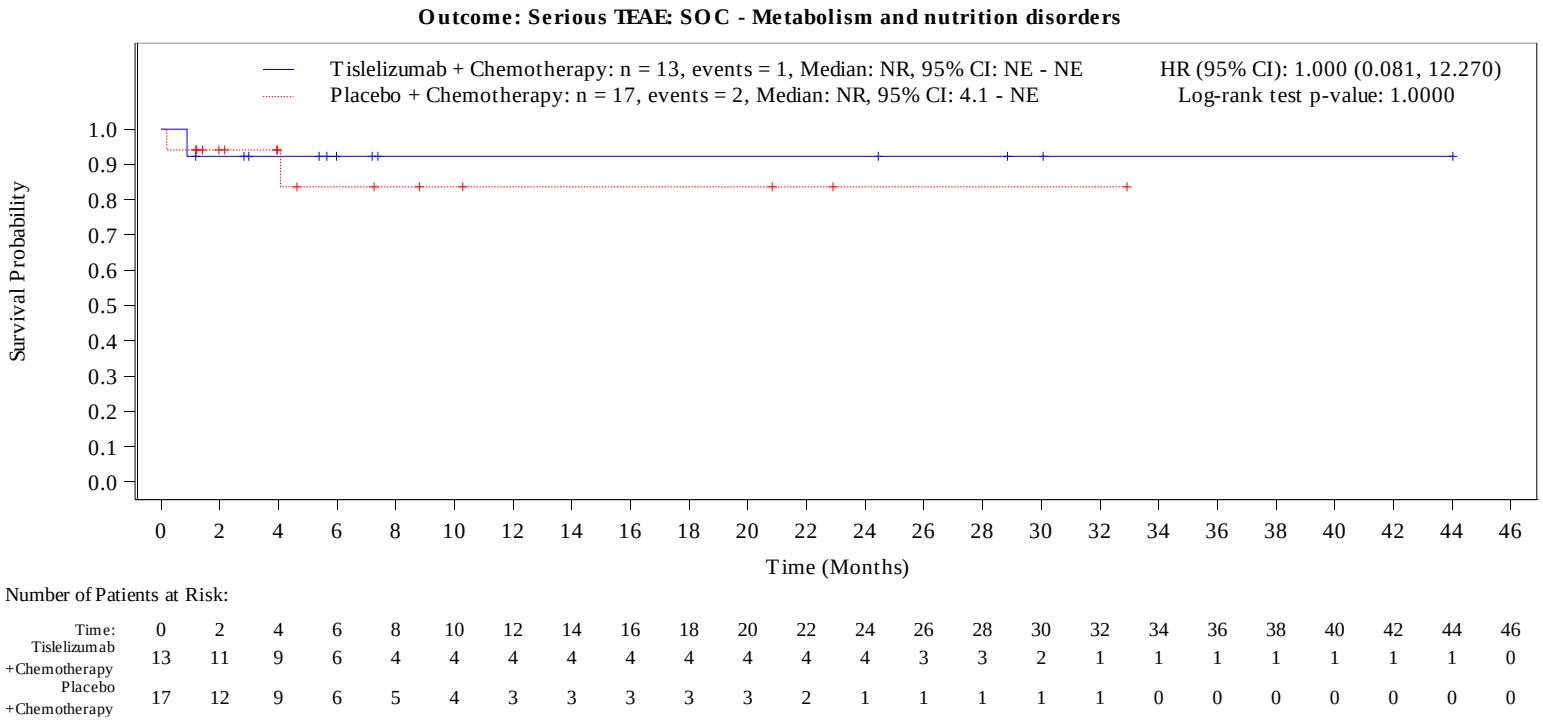
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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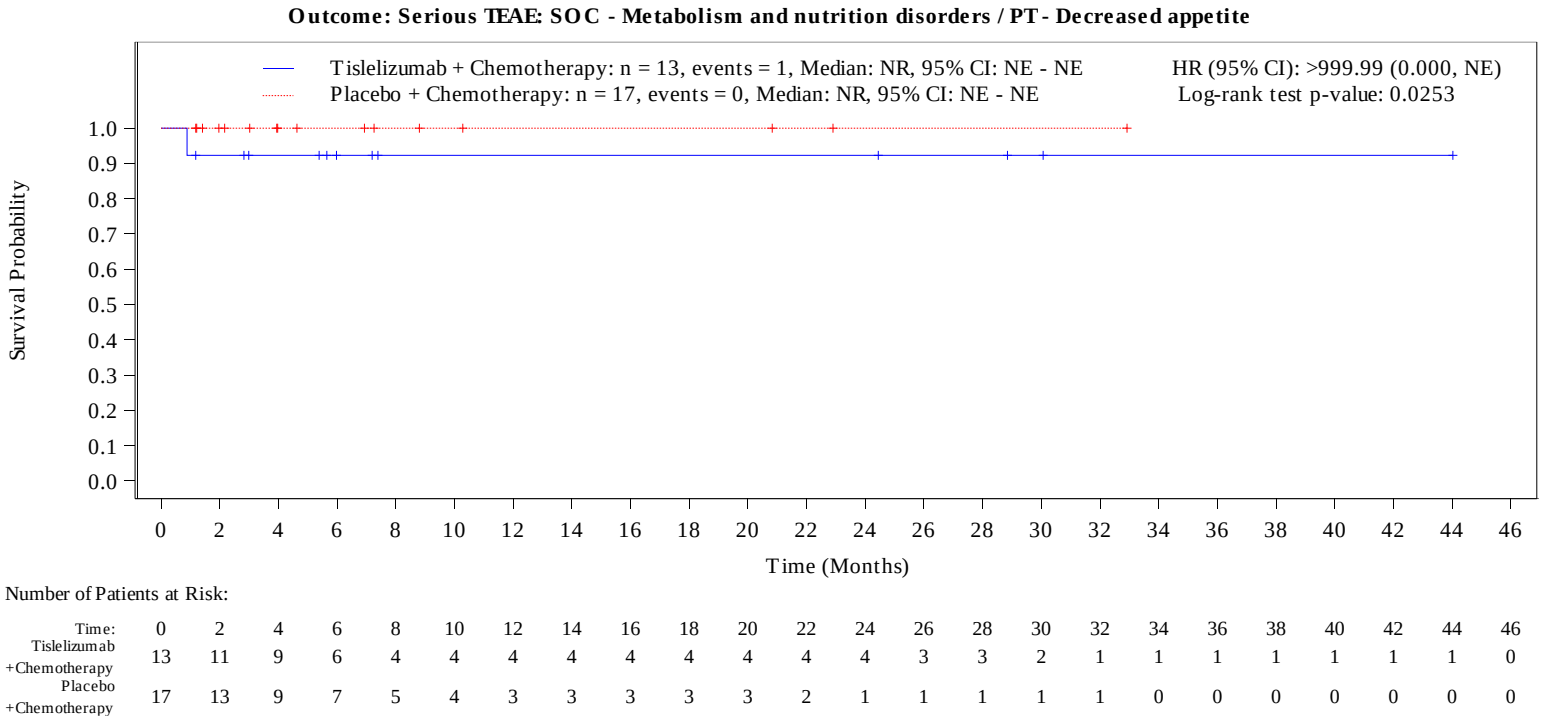

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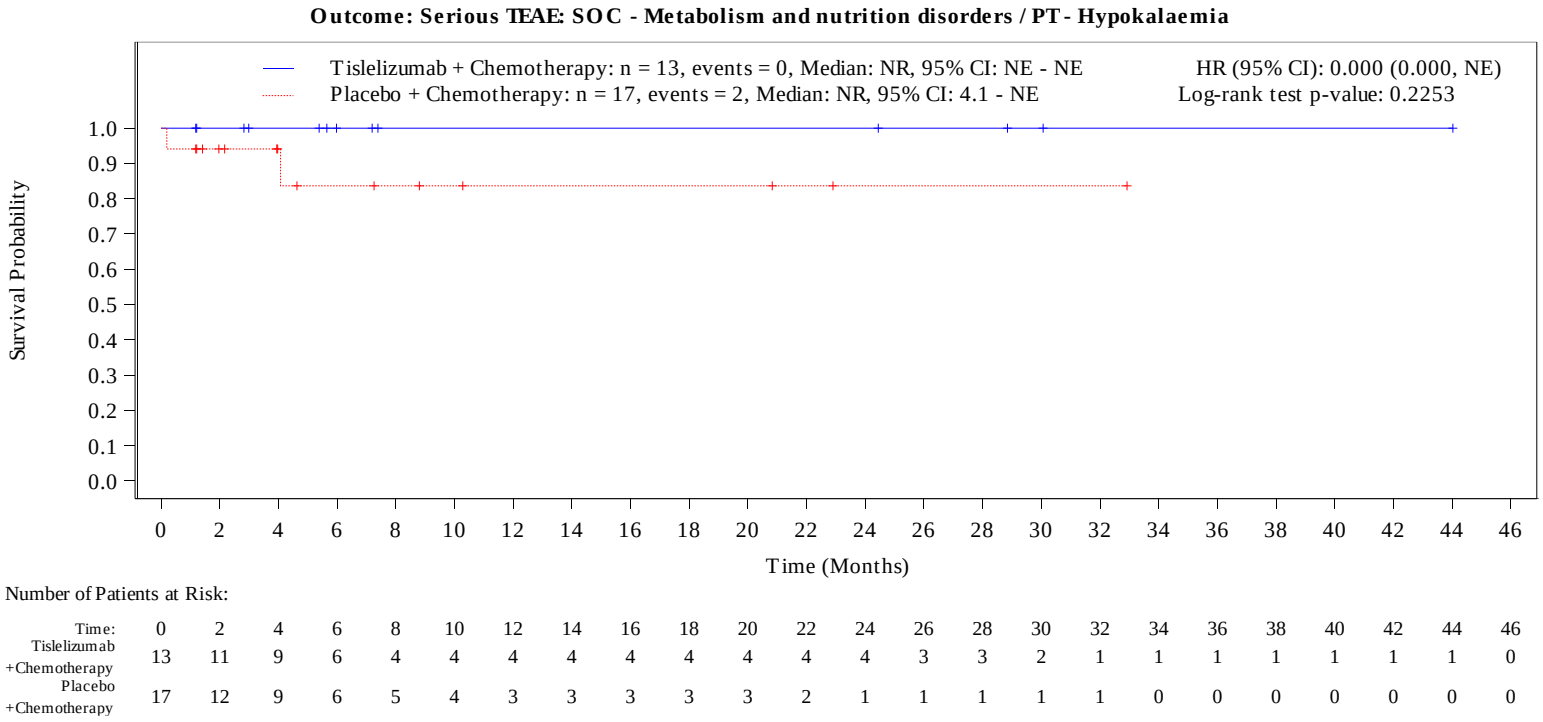

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Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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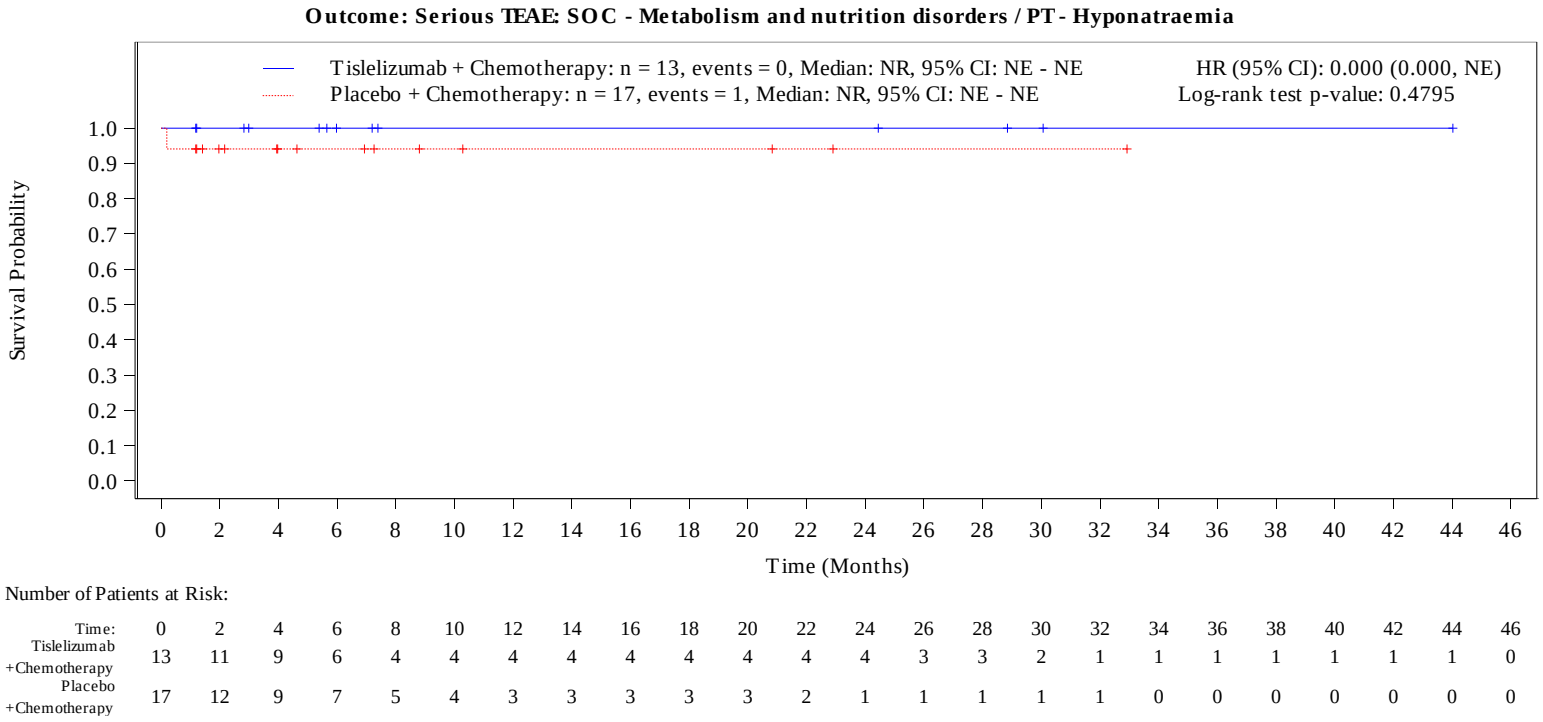

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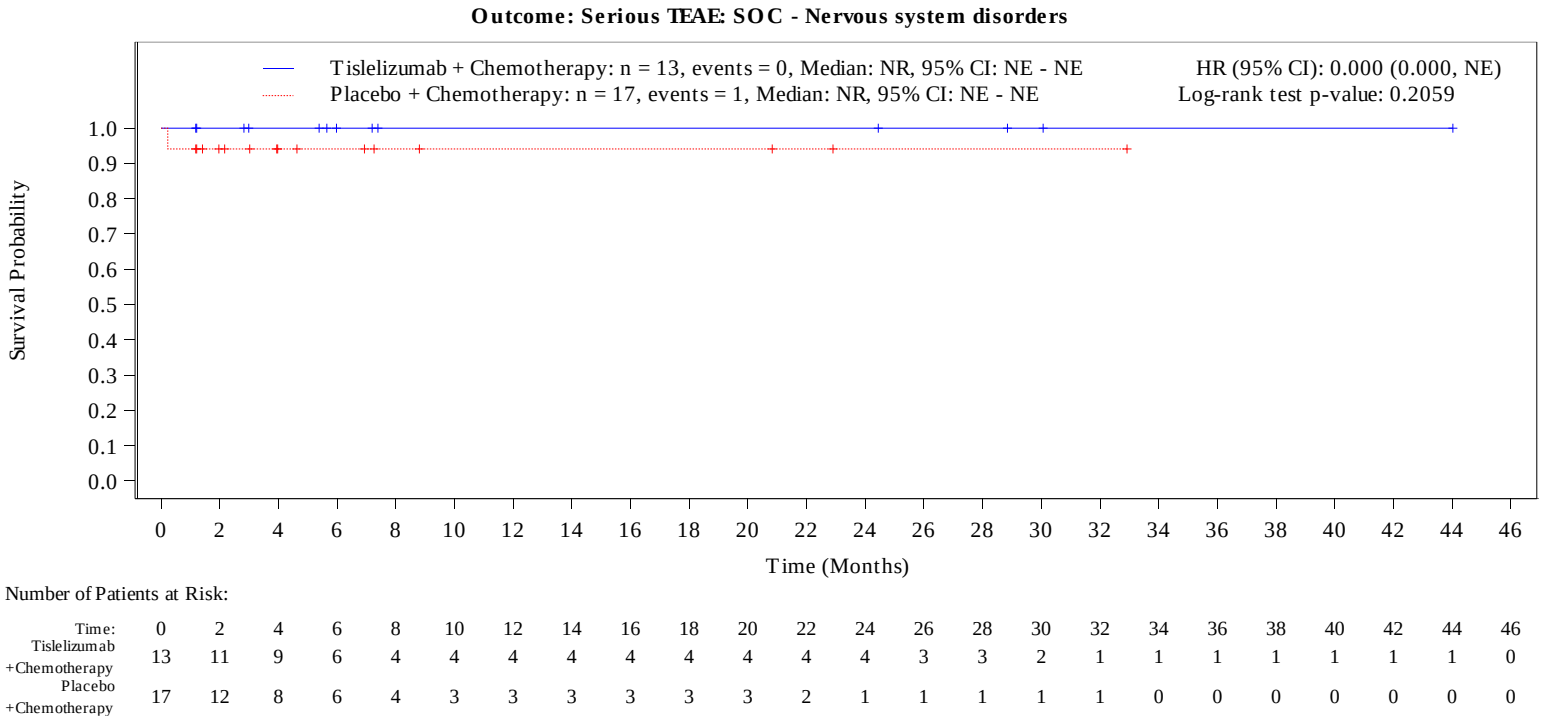

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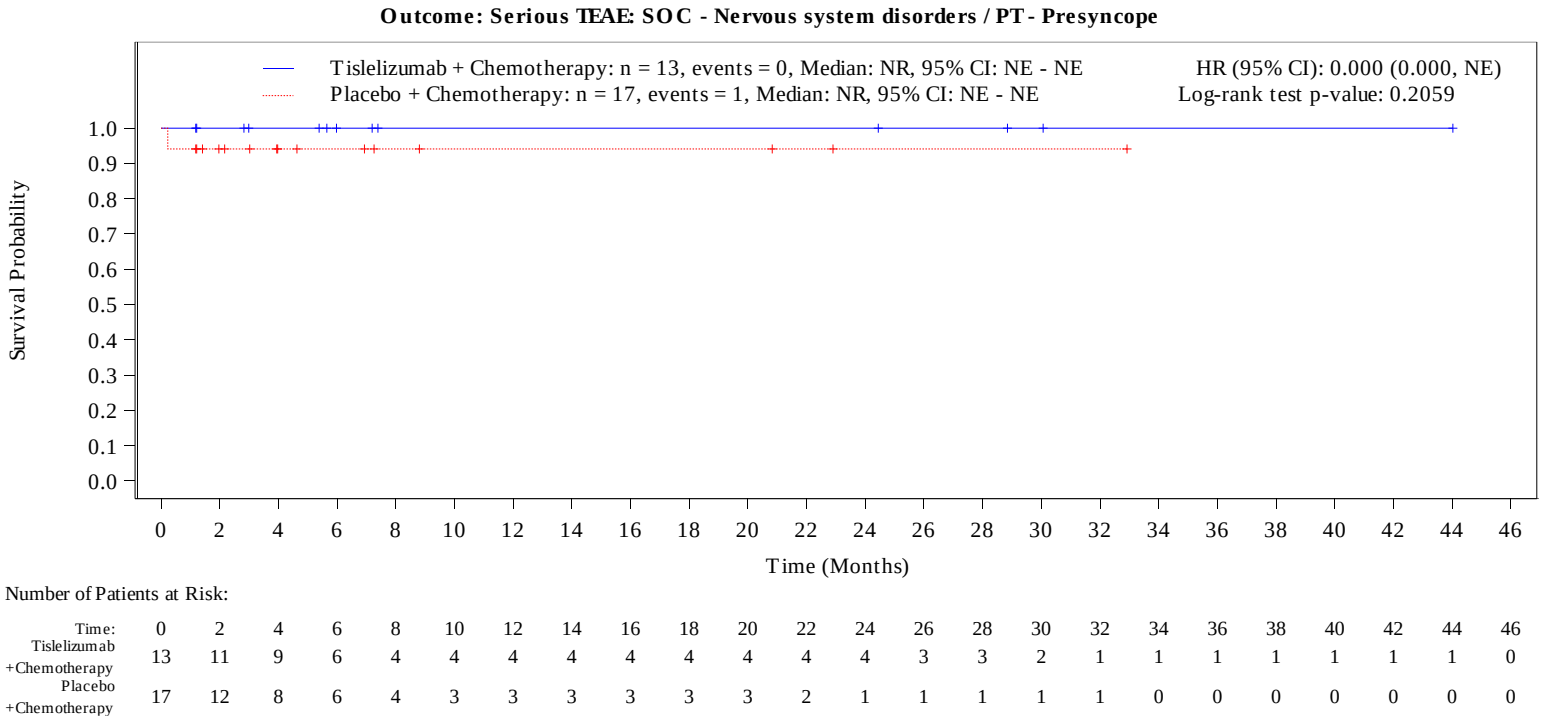

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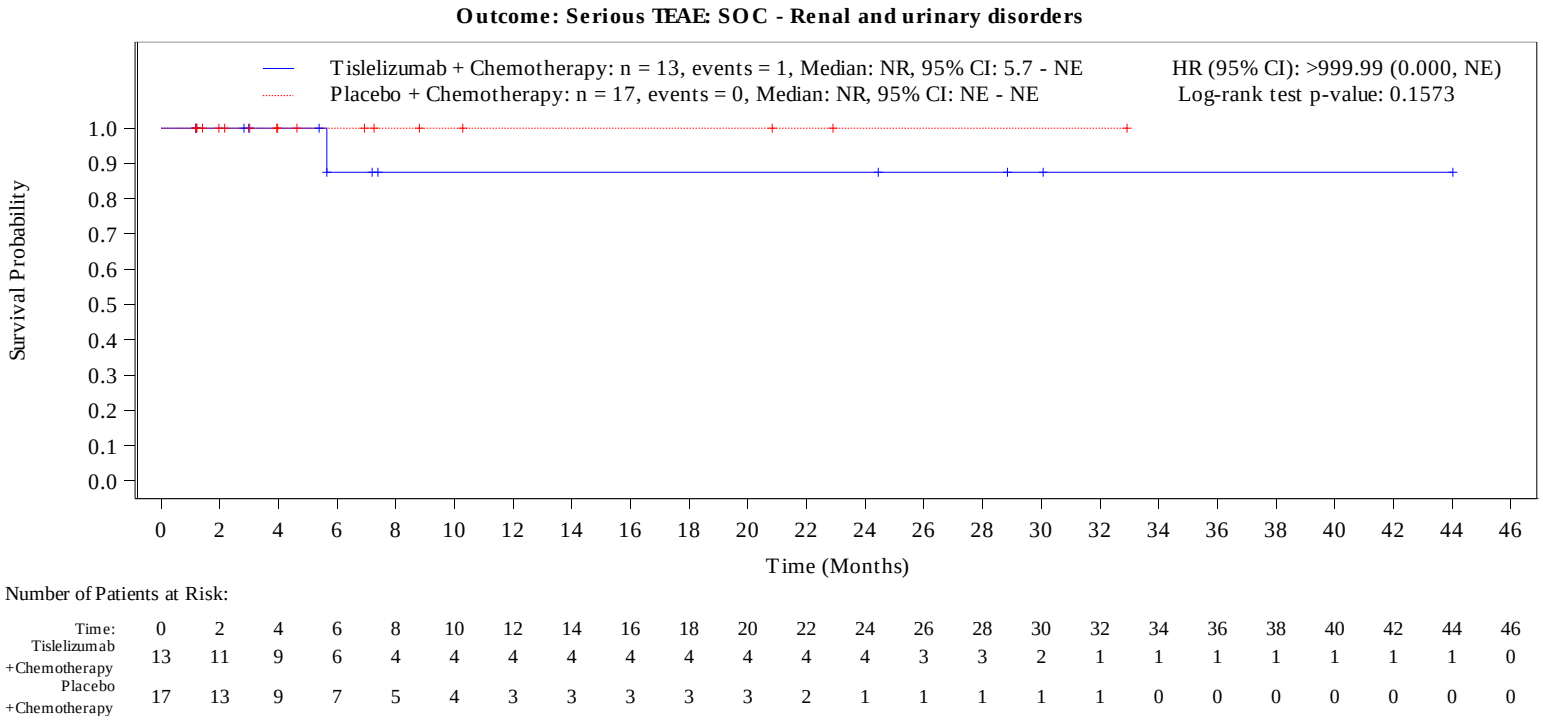
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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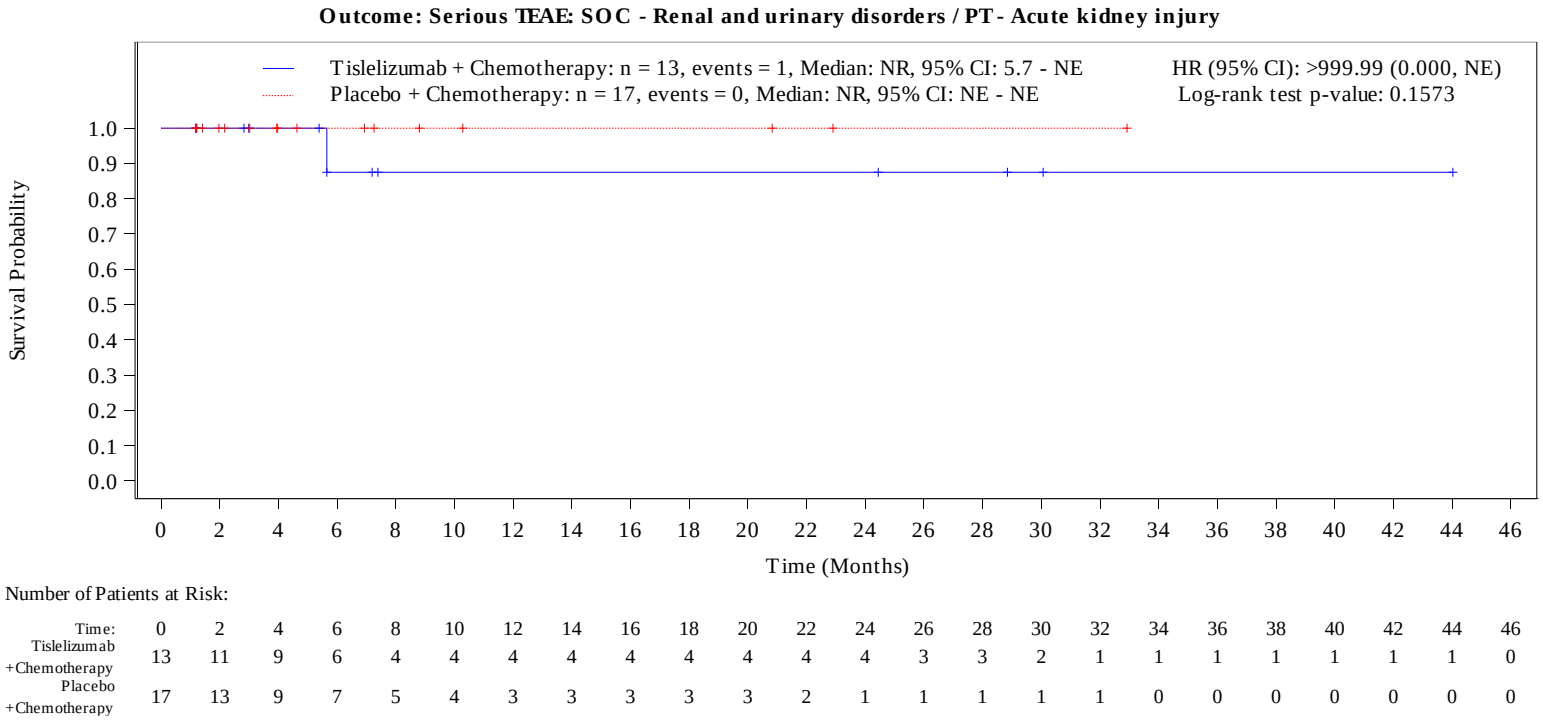
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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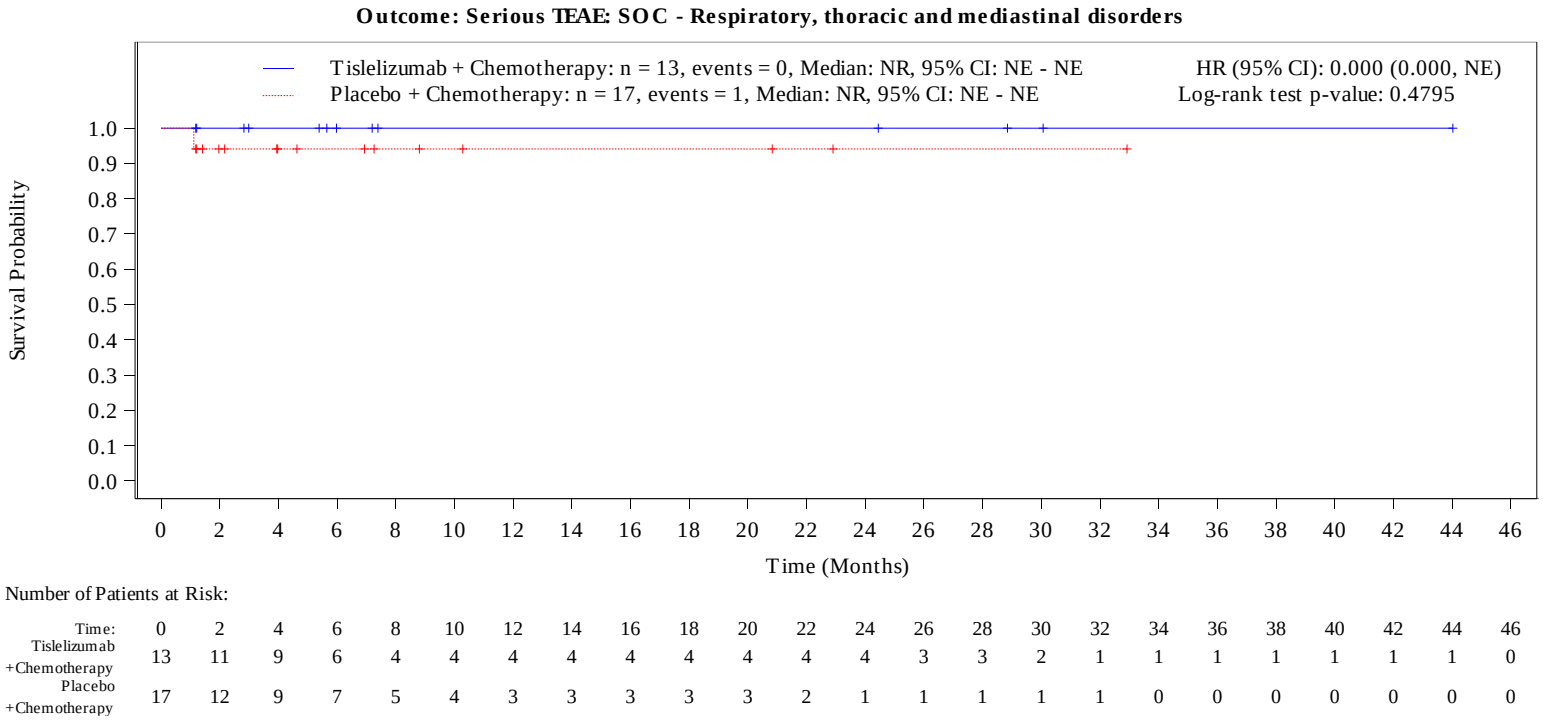
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

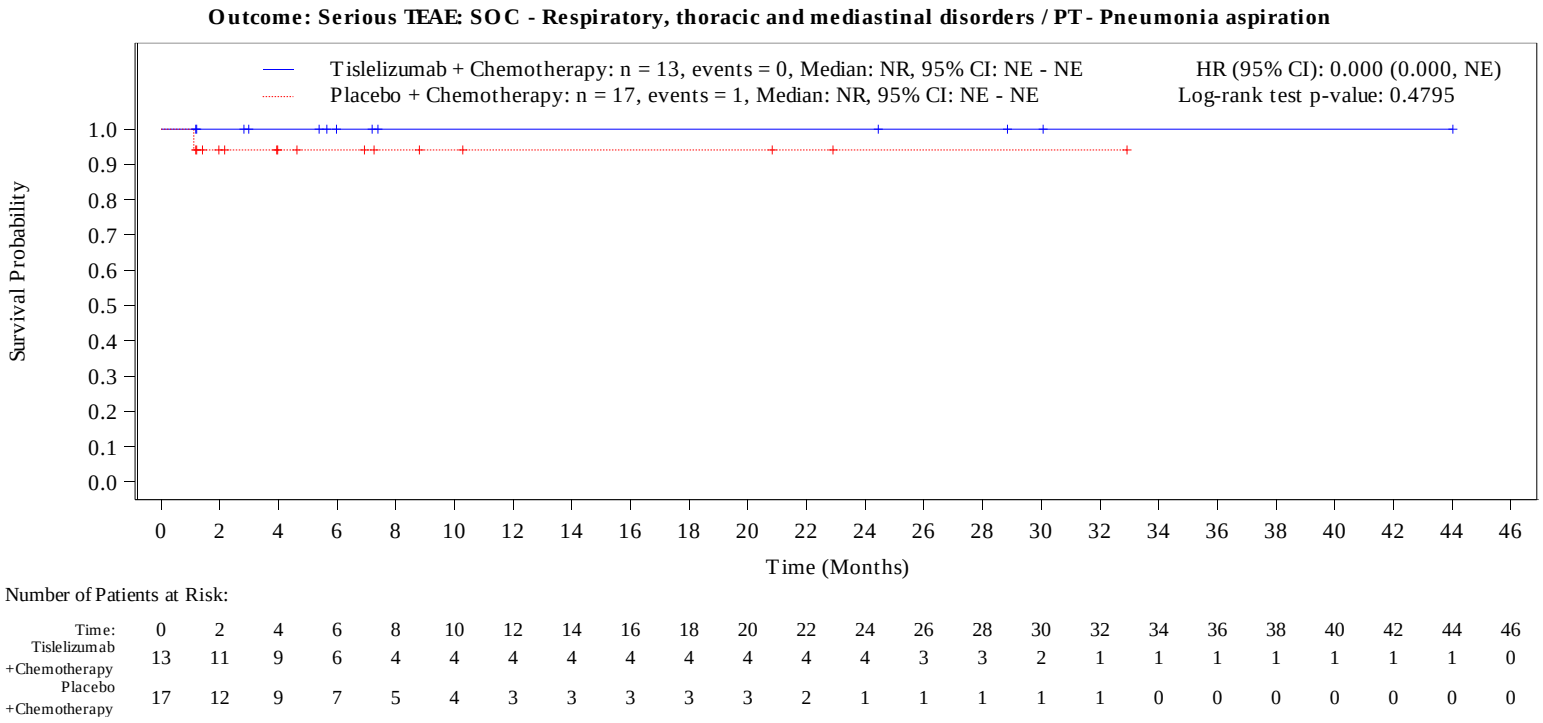

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	7 (77.8)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	6 (66.7)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	2 (20.0)	--	--	--
1	6	5 (83.3)	--	7	2 (28.6)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	--	7	2 (28.6)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	3 (50.0)	--	7	1 (14.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	4 (44.4)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	6 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	2 (50.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	6 (60.0)	--	--	--
1	6	2 (33.3)	--	7	3 (42.9)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	1 (25.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	2 (33.3)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Table 14.3.1.2.4.1.1.s:
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Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

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Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: TEAE, treatment-emergent adverse event.

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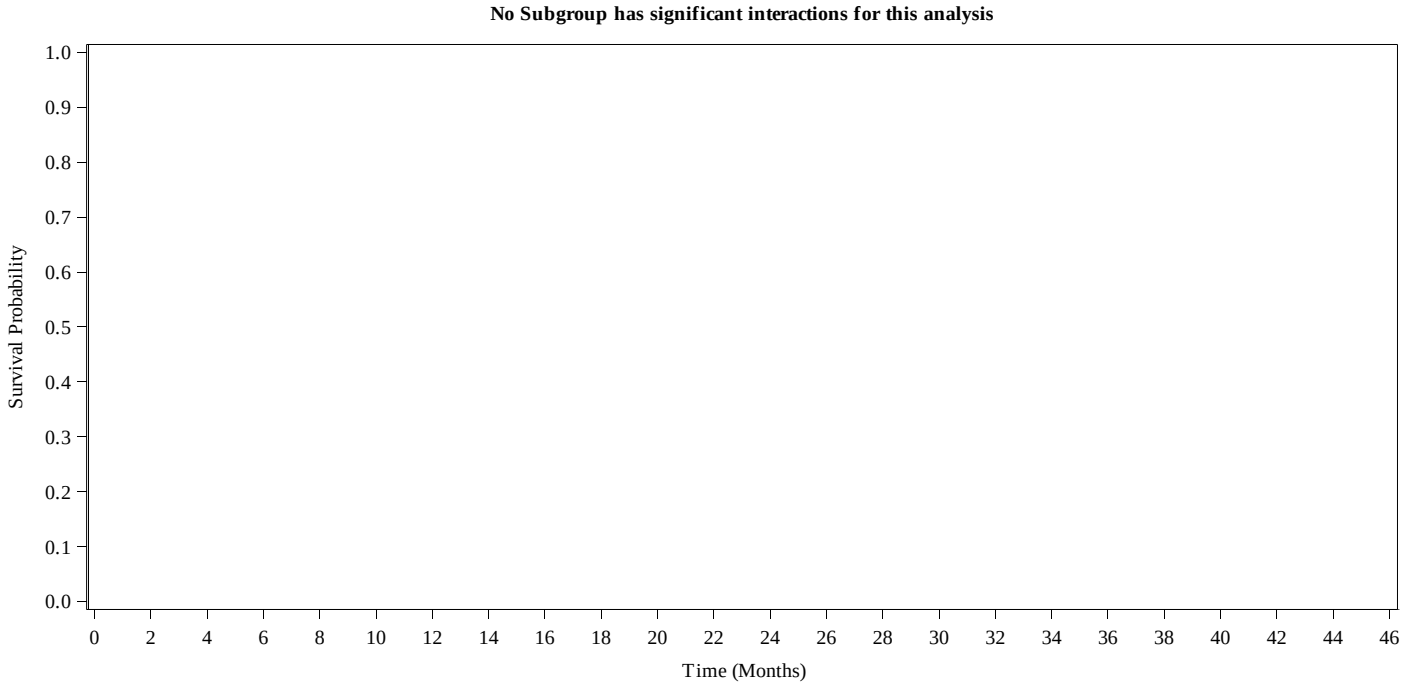
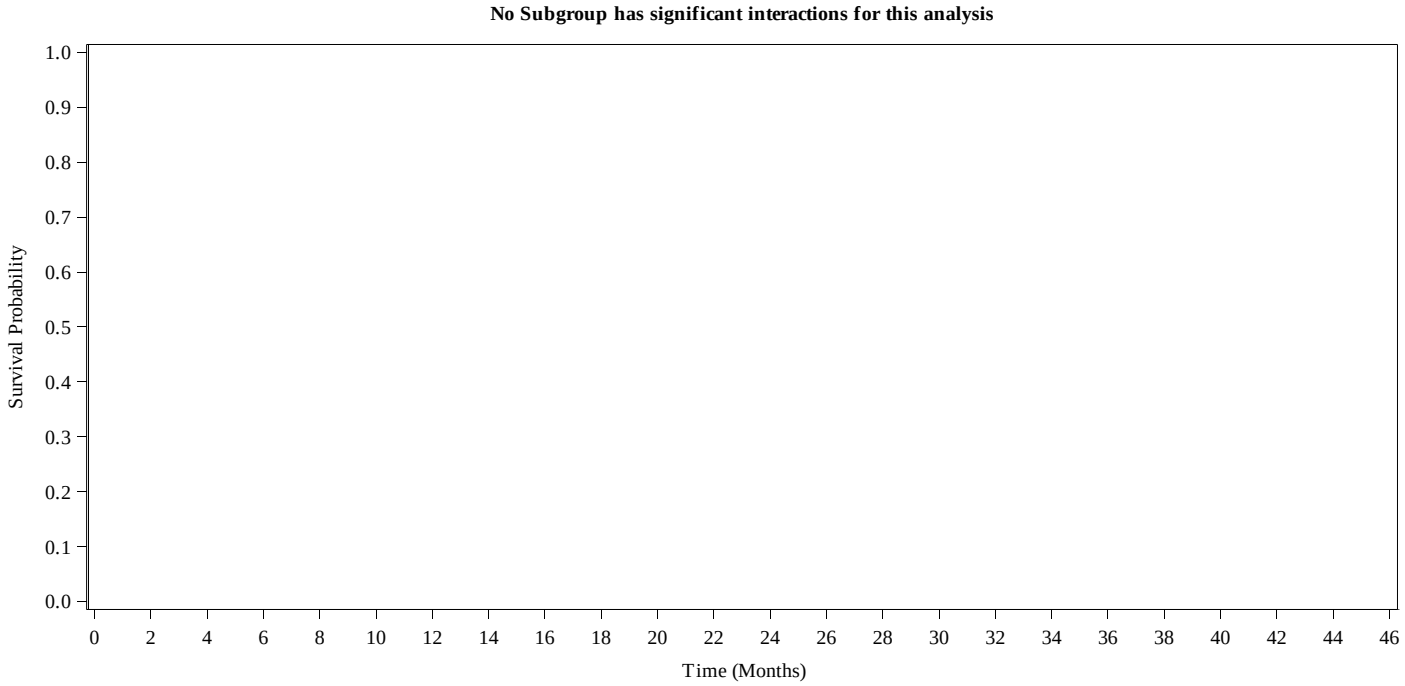
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



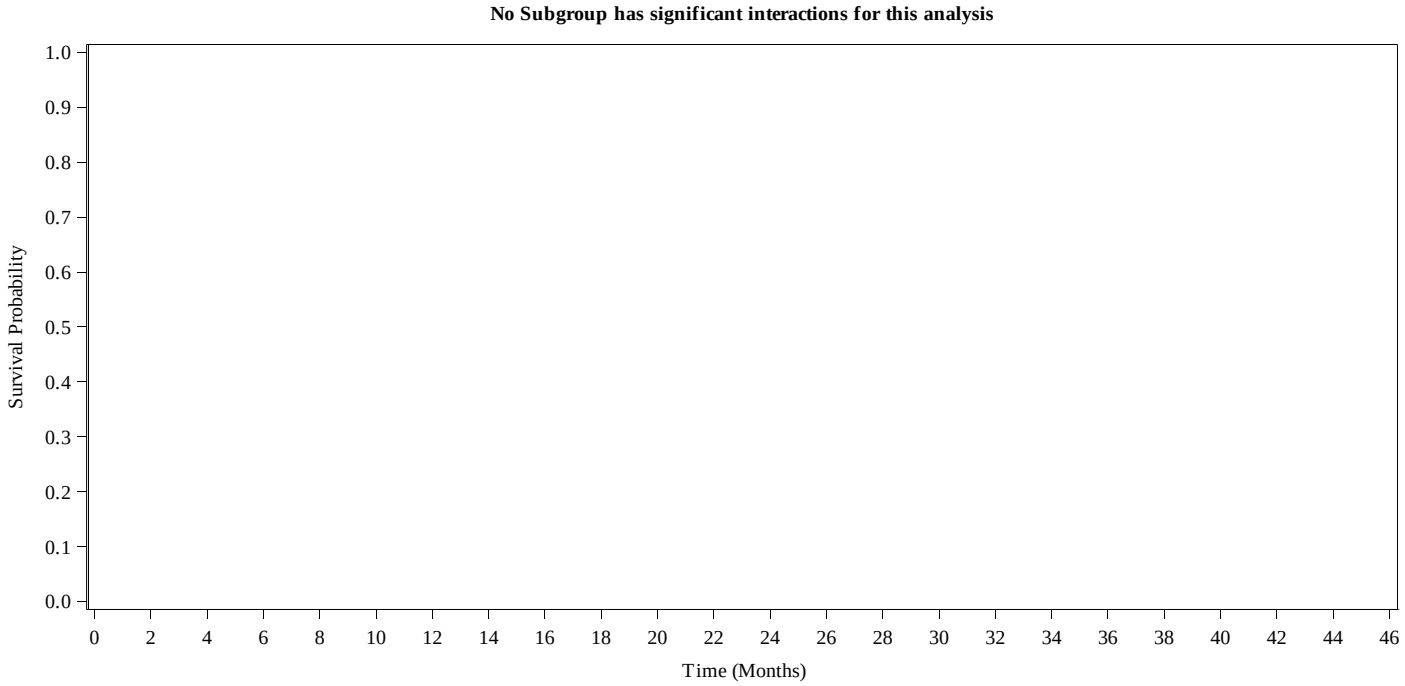
Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any imAE	13	5 (38.5)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.186 (0.261, 5.396)	0.8252
imAE of Grade 1 and 2	13	4 (30.8)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.081 (0.226, 5.165)	0.9220
imAE >= Grade 3	13	2 (15.4)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Serious imAE	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5930

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR of Grade 1 and 2	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR >= Grade 3	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Adverse events were graded for severity using CTCAE v4.03.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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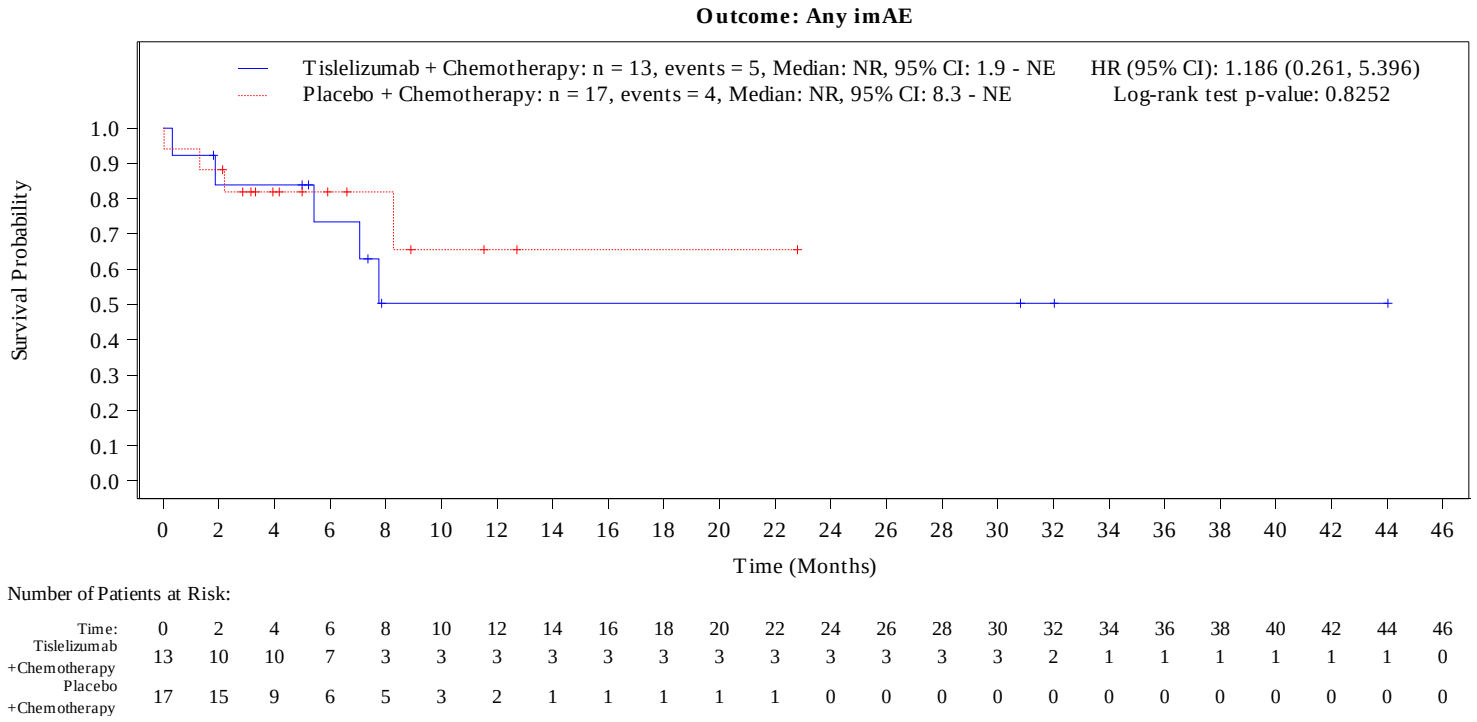
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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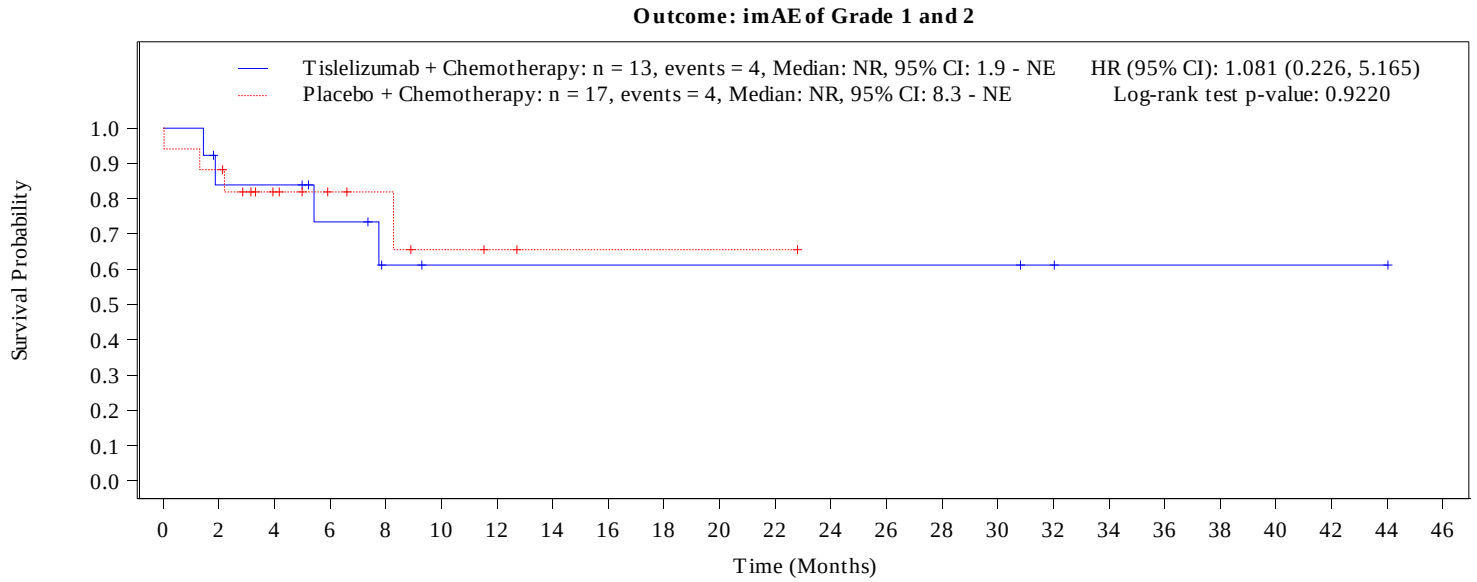
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab +Chemotherapy	13	10	10	7	4	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	15	9	6	5	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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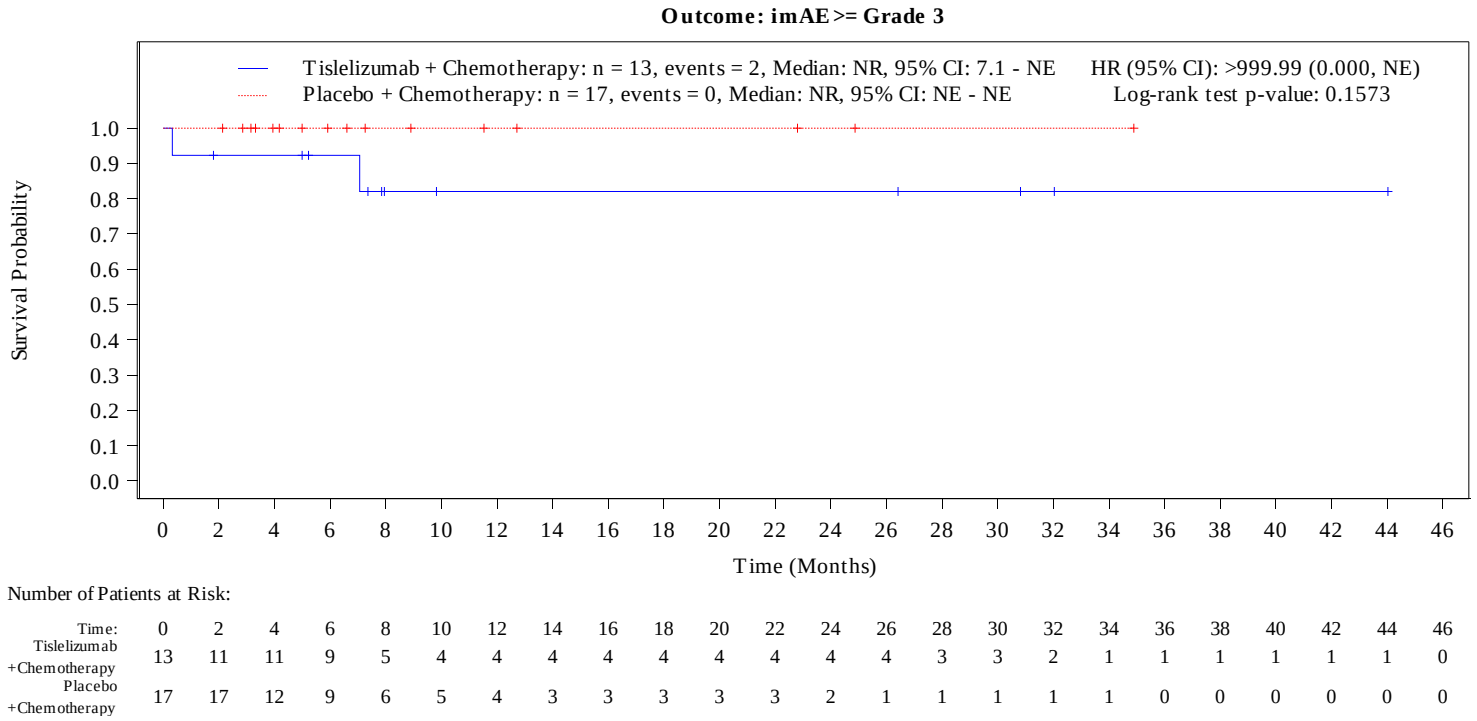
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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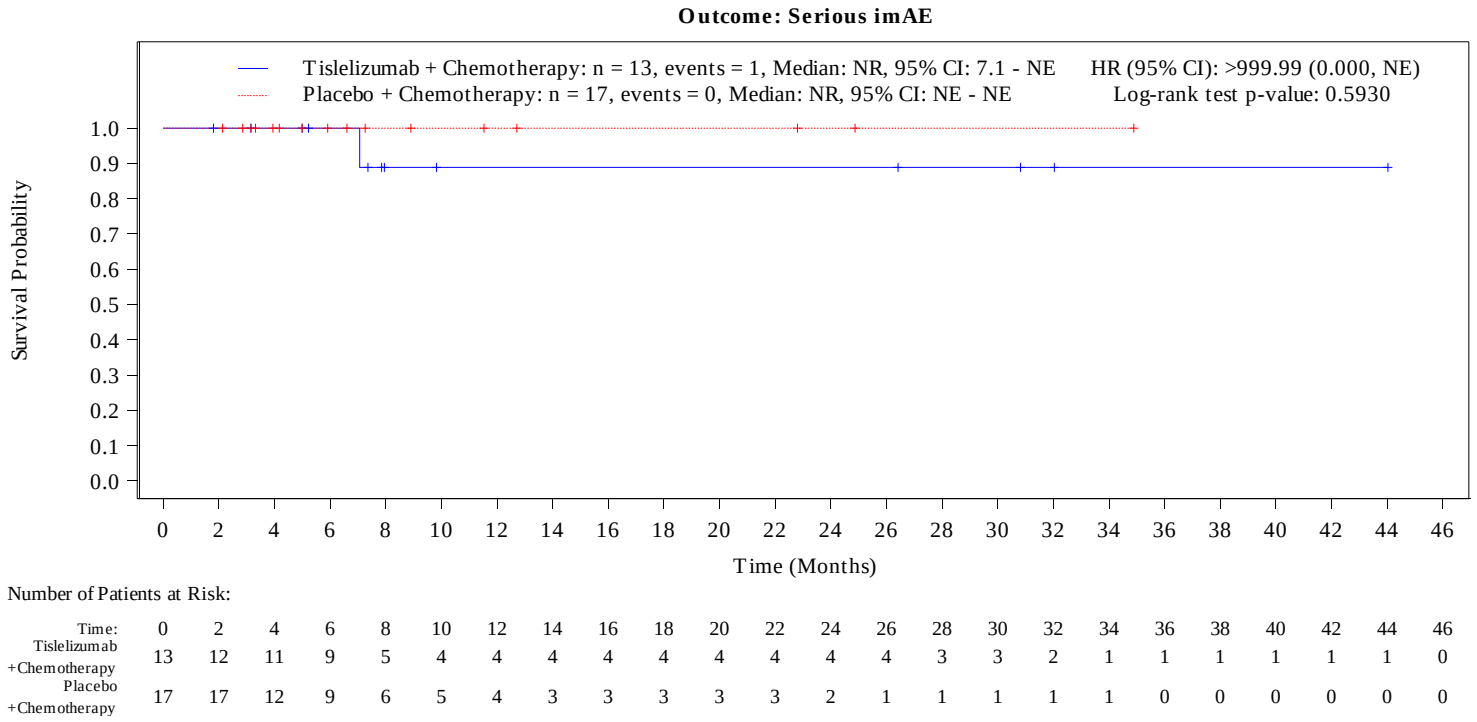
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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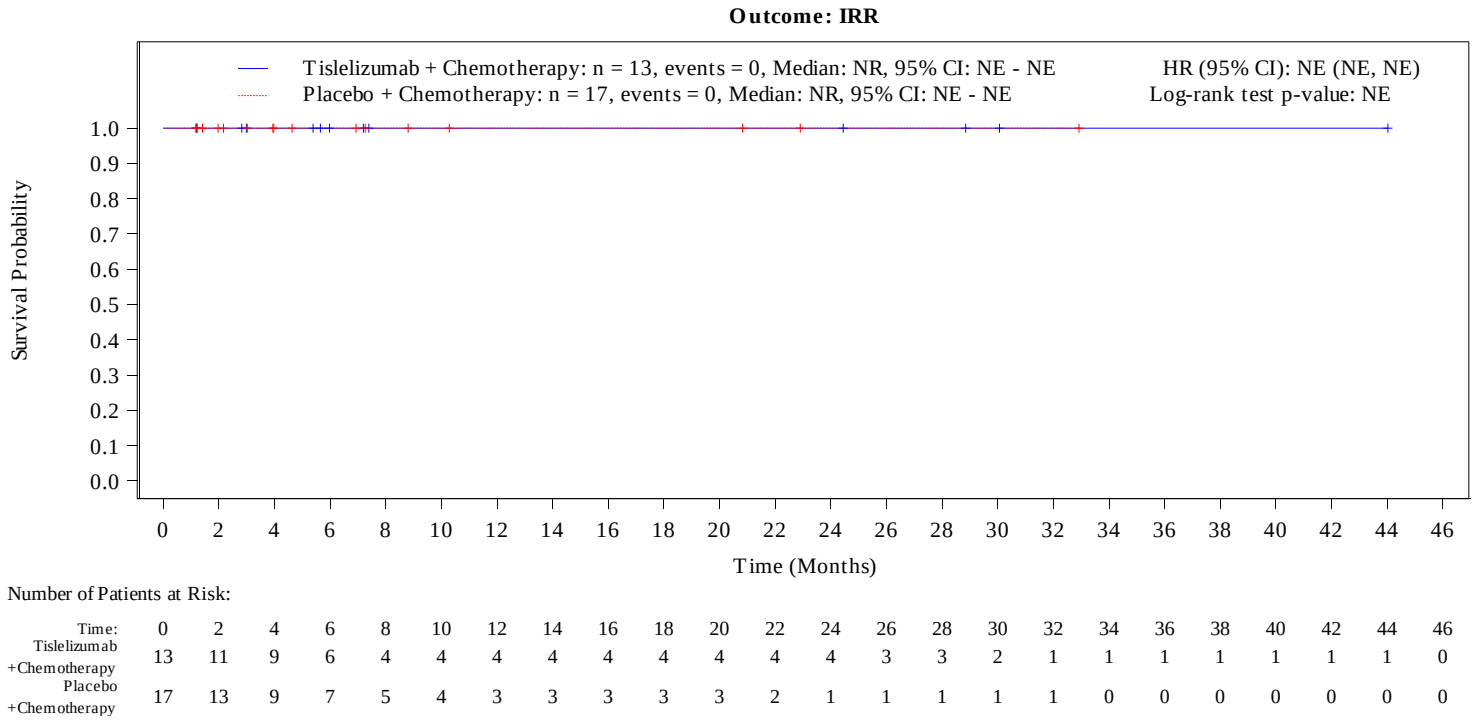
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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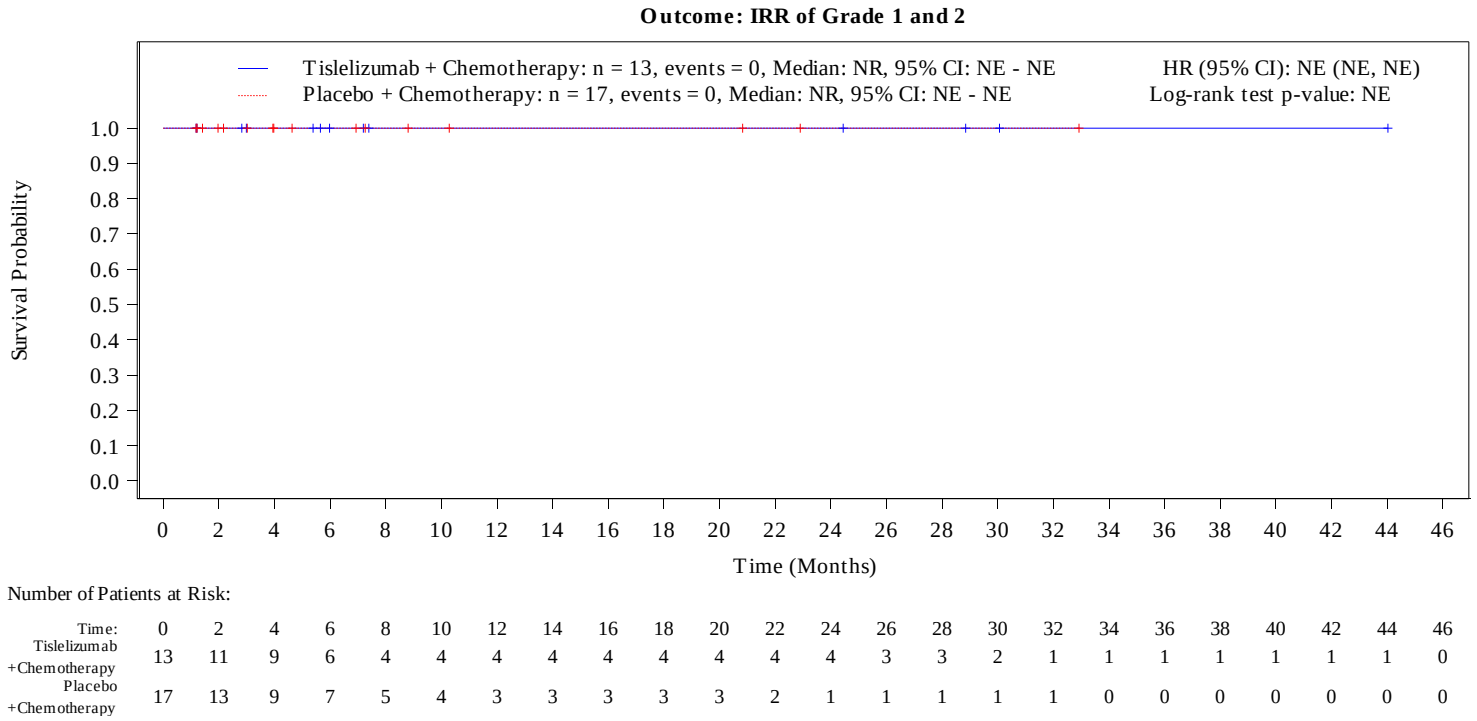
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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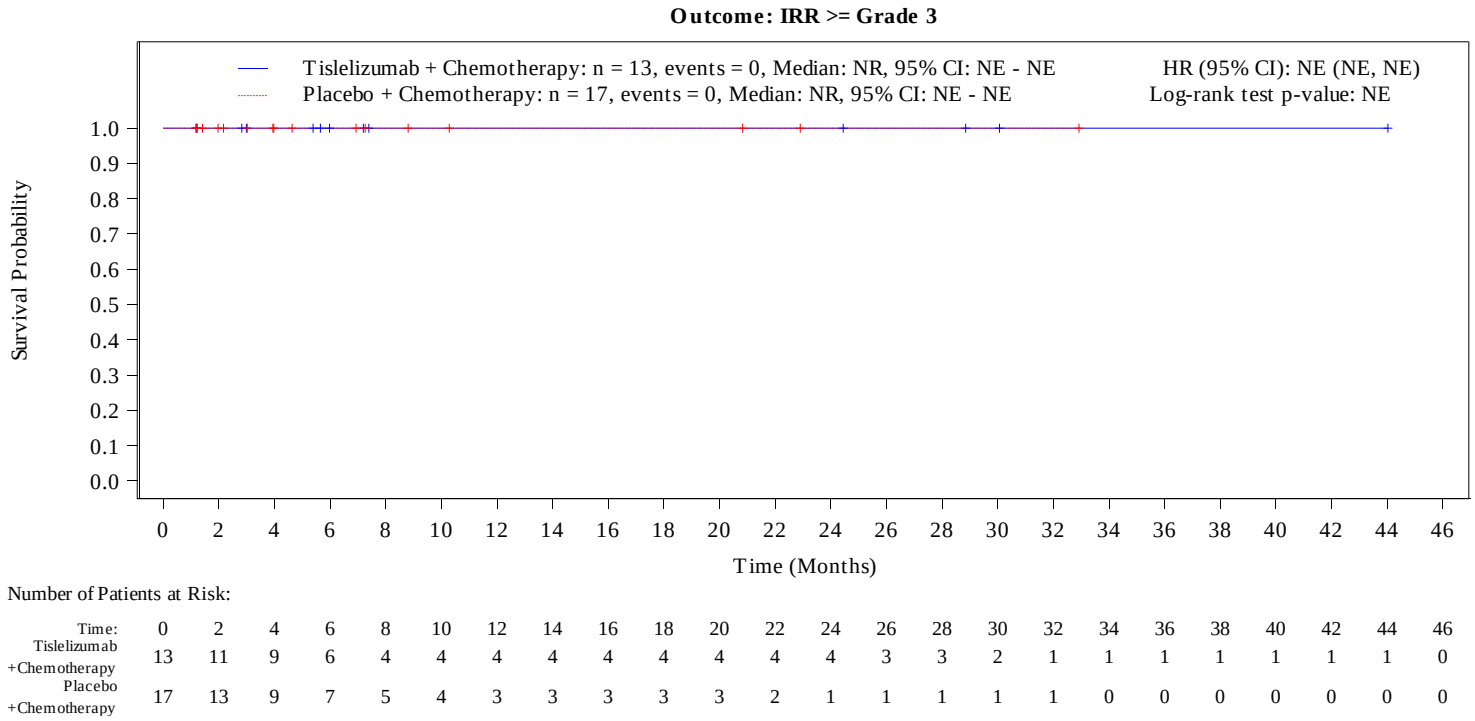
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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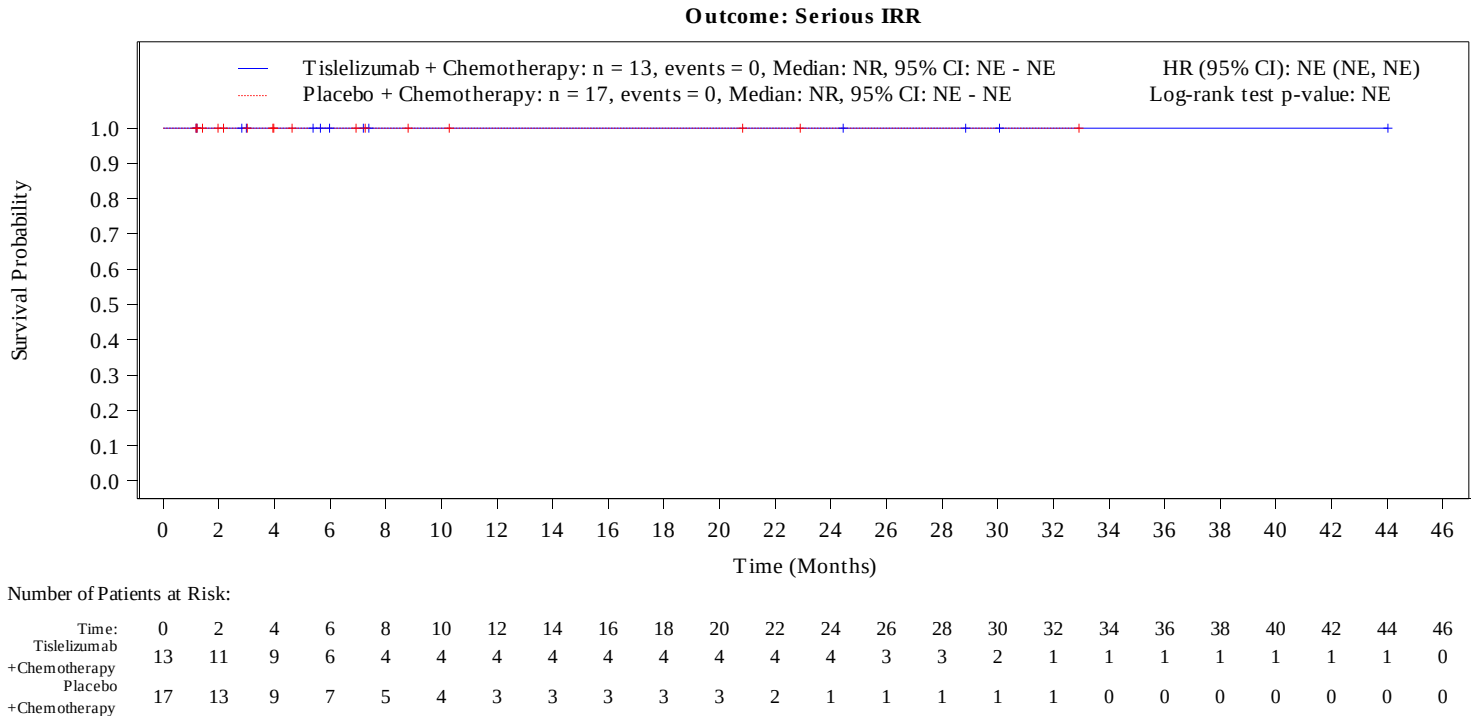
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	3 (33.3)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	3 (33.3)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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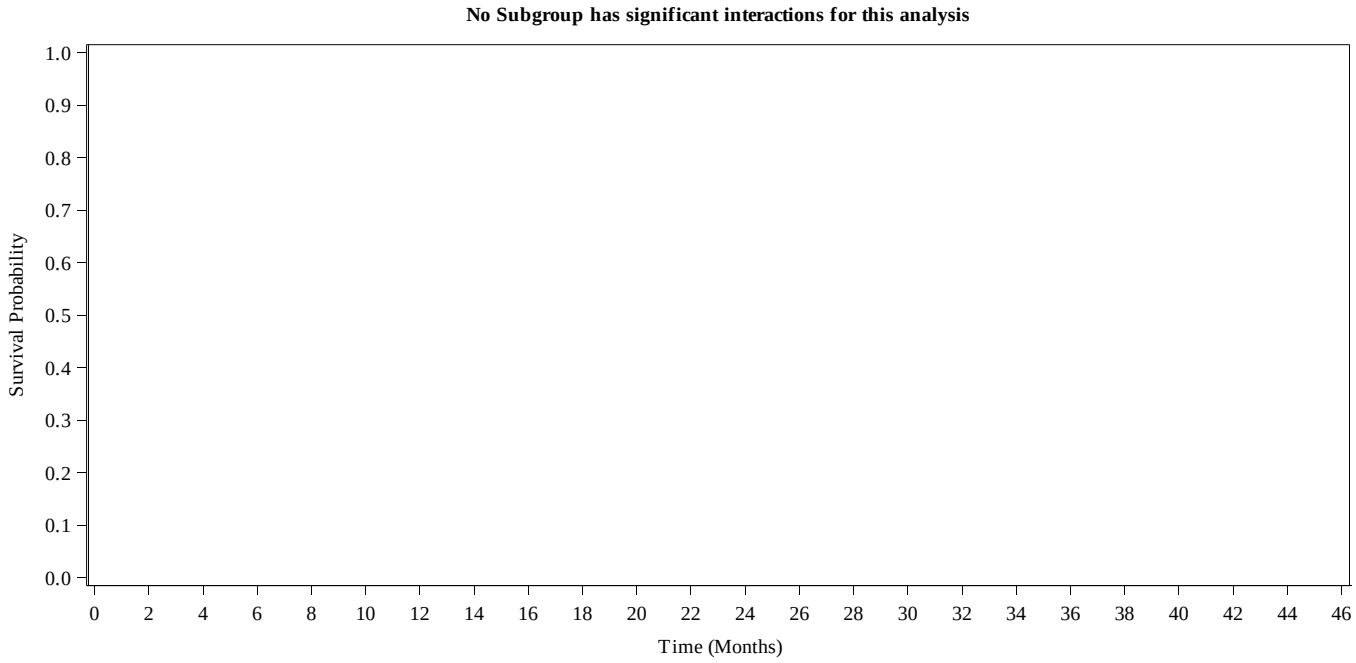
Figure 14.3.1.5.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 28APR2023. Data extraction: 09JUN2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Adverse events were graded for severity using CTCAE v4.03. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Number of Patients Randomized	13 (100.0)	17 (100.0)	30 (100.0)
Patients Randomized, But not Treated	0 (0.0)	0 (0.0)	0 (0.0)
Primary Reason for not Treated [a]			
Number of Patients Treated	13 (100.0)	17 (100.0)	30 (100.0)
Number of Patients Discontinued from Treatment	12 (92.3)	17 (100.0)	29 (96.7)

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
[a] Patients randomized but not treated with any treatment component.
[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.
[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.
[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.
[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Drug Discontinuation [b]			
Progressive Disease	7 (53.8)	12 (70.6)	19 (63.3)
Radiographic Progression	6 (46.2)	11 (64.7)	17 (56.7)
Clinical Progression	1 (7.7)	1 (5.9)	2 (6.7)
Withdrawal by Subject	3 (23.1)	2 (11.8)	5 (16.7)
Adverse Event	1 (7.7)	2 (11.8)	3 (10.0)
Treatment-interruption [c]	1 (7.7)	0 (0.0)	1 (3.3)
Other	0 (0.0)	1 (5.9)	1 (3.3)
Number of Patients Remained on Treatment	1 (7.7)	0 (0.0)	1 (3.3)
Number of Patients Discontinued from Study	7 (53.8)	14 (82.4)	21 (70.0)

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Discontinuation			
Death	7 (53.8)	12 (70.6)	19 (63.3)
Lost to Follow-up	0 (0.0)	1 (5.9)	1 (3.3)
Withdrawal by Subject	0 (0.0)	1 (5.9)	1 (3.3)
Number of Patients Remained on Study	6 (46.2)	3 (17.6)	9 (30.0)
Study Follow-up Duration [d] (months)			
n	13	17	30
Mean (SD)	30.0 (16.31)	17.7 (15.67)	23.0 (16.85)
Median	26.5	9.8	19.8
Q1, Q3	19.1, 44.8	7.0, 23.8	8.0, 40.0
Min, Max	1.8, 50.9	2.2, 46.1	1.8, 50.9

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Minimum Study Follow-Up Time [e] (months)	39.0	38.3	38.3

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.) or to the cutoff date if a patient is still ongoing.

[e] Minimum study follow-up time is defined as a difference between the date of cutoff and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Age (years)			
n	13	17	30
Mean (SD)	59.7 (7.48)	65.1 (7.94)	62.8 (8.08)
Median	60.0	66.0	62.5
Q1, Q3	57.0, 65.0	59.0, 72.0	58.0, 69.0
Min, Max	46, 69	47, 76	46, 76
Age Group, n (%)			
< 65 years	9 (69.2)	8 (47.1)	17 (56.7)
≥ 65 years	4 (30.8)	9 (52.9)	13 (43.3)
Sex, n (%)			
Female	4 (30.8)	6 (35.3)	10 (33.3)
Male	9 (69.2)	11 (64.7)	20 (66.7)
Region, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Asia (excluding Japan)	6 (46.2)	2 (11.8)	8 (26.7)
Japan	5 (38.5)	9 (52.9)	14 (46.7)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Race, n (%)			
Asian	11 (84.6)	11 (64.7)	22 (73.3)
Chinese	5 (38.5)	1 (5.9)	6 (20.0)
Japanese	5 (38.5)	9 (52.9)	14 (46.7)
Korean	1 (7.7)	1 (5.9)	2 (6.7)
White	2 (15.4)	5 (29.4)	7 (23.3)
American Indian or Alaska Native	0 (0.0)	1 (5.9)	1 (3.3)
Ethnicity, n (%)			
Hispanic or Latino	0 (0.0)	1 (5.9)	1 (3.3)
Not Hispanic or Latino	13 (100.0)	16 (94.1)	29 (96.7)
ECOG Status, n (%)			
0	7 (53.8)	10 (58.8)	17 (56.7)
1	6 (46.2)	7 (41.2)	13 (43.3)

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
BMI (kg/m^2)			
n	13	17	30
Mean (SD)	21.92 (3.553)	21.20 (3.497)	21.51 (3.479)
Median	21.63	20.91	21.40
Q1, Q3	21.10, 22.86	19.20, 23.31	20.20, 23.31
Min, Max	14.3, 28.3	15.9, 29.2	14.3, 29.2
Tobacco Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	9 (69.2)	12 (70.6)	21 (70.0)
Current	1 (7.7)	1 (5.9)	2 (6.7)
Alcohol Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	8 (61.5)	10 (58.8)	18 (60.0)
Current	2 (15.4)	2 (11.8)	4 (13.3)
Missing	0 (0.0)	1 (5.9)	1 (3.3)
Pooled Geographic Region per IRT, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Definitive Therapy per IRT, n (%)			
Yes	4 (30.8)	7 (41.2)	11 (36.7)
No	9 (69.2)	10 (58.8)	19 (63.3)

Source: ADSL. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Time from Initial Diagnosis to Study Entry (months)			
n	13	17	30
Mean (SD)	8.30 (16.077)	8.16 (15.719)	8.22 (15.598)
Median	0.95	1.81	1.12
Q1, Q3	0.76, 12.48	0.82, 11.10	0.76, 12.09
Min, Max	0.5, 58.2	0.2, 65.7	0.2, 65.7
Primary Site of Esophageal Cancer, n (%)			
Cervical	0 (0.0)	3 (17.6)	3 (10.0)
Upper thoracic	5 (38.5)	4 (23.5)	9 (30.0)
Middle thoracic	4 (30.8)	5 (29.4)	9 (30.0)
Lower thoracic	4 (30.8)	5 (29.4)	9 (30.0)

Source: ADSL, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Histologic Grade, n (%)			
Gx - Grade cannot be assessed	5 (38.5)	8 (47.1)	13 (43.3)
G1 - Well-differentiated	1 (7.7)	2 (11.8)	3 (10.0)
G2 - Moderately-differentiated	6 (46.2)	6 (35.3)	12 (40.0)
G3 - Poorly differentiated	1 (7.7)	1 (5.9)	2 (6.7)
Histologic Type, n (%)			
Squamous Cell Carcinoma	13 (100.0)	17 (100.0)	30 (100.0)
Other [a]	0 (0.0)	0 (0.0)	0 (0.0)
Disease Stage at Diagnosis [b], n (%)			
Stage I (IA, IB)	1 (7.7)	1 (5.9)	2 (6.7)
Stage II (IIA, IIB)	1 (7.7)	2 (11.8)	3 (10.0)
Stage III (IIIA, IIIB, IIIC)	3 (23.1)	5 (29.4)	8 (26.7)
Stage IV	8 (61.5)	9 (52.9)	17 (56.7)

Source: ADSL, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.

Study Entry date referred to randomization date in this study.

[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.

[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.

[c] A patient was counted only once within each category, but may be counted in multiple categories.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Disease Status at Study Entry, n (%)			
Metastatic	12 (92.3)	15 (88.2)	27 (90.0)
Locally Advanced	1 (7.7)	2 (11.8)	3 (10.0)
Time from Metastatic Disease to Study Entry (months)			
n	12	15	27
Mean (SD)	1.30 (1.812)	3.51 (10.275)	2.53 (7.713)
Median	0.74	0.72	0.72
Q1, Q3	0.53, 1.33	0.33, 1.38	0.46, 1.35
Min, Max	0.3, 6.9	0.0, 40.6	0.0, 40.6
Number of Metastatic Sites at Study Entry, n (%)			
0	1 (7.7)	2 (11.8)	3 (10.0)
1	9 (69.2)	8 (47.1)	17 (56.7)
2	2 (15.4)	5 (29.4)	7 (23.3)
>2	1 (7.7)	2 (11.8)	3 (10.0)

Source: ADSL, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Locations of Metastases at Study Entry [c], n (%)			
Lymph Nodes	7 (53.8)	6 (35.3)	13 (43.3)
Lung	6 (46.2)	7 (41.2)	13 (43.3)
Liver	2 (15.4)	4 (23.5)	6 (20.0)
Bone	1 (7.7)	1 (5.9)	2 (6.7)
Brain	0 (0.0)	0 (0.0)	0 (0.0)
Peritoneum	0 (0.0)	0 (0.0)	0 (0.0)
Skin	0 (0.0)	0 (0.0)	0 (0.0)
Soft Tissue	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	6 (35.3)	6 (20.0)

Source: ADSL, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Target Lesions Sum of Diameter by Investigator (mm)			
n	13	15	28
Mean (SD)	30.95 (18.422)	54.19 (28.241)	43.40 (26.527)
Median	27.20	54.62	31.00
Q1, Q3	17.00, 43.20	27.00, 75.00	21.35, 62.36
Min, Max	10.4, 67.0	18.8, 109.0	10.4, 109.0
PD-L1 Status, n (%)			
PD-L1 Score < 10%	13 (100.0)	17 (100.0)	30 (100.0)

Source: ADSL, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.

Study Entry date referred to randomization date in this study.

[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.

[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.

[c] A patient was counted only once within each category, but may be counted in multiple categories.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Patients with at Least One Prior Definitive Therapy, n (%) [a]	4 (30.8)	7 (41.2)	11 (36.7)
Definitive Radiotherapy with/without Chemotherapy	0 (0.0)	1 (5.9)	1 (3.3)
Definitive Surgery with/without Adjuvant/Neo-adjuvant Treatment	4 (30.8)	6 (35.3)	10 (33.3)
Time from End of Last Prior Anti-Cancer Therapy to Study Entry [b] (months)			
n	4	8	12
Mean (SD)	22.71 (23.656)	30.69 (58.484)	28.03 (48.422)
Median	13.27	9.82	10.12
Q1, Q3	9.56, 35.86	7.39, 18.07	7.39, 19.81
Min, Max	6.4, 57.9	0.6, 174.4	0.6, 174.4
Prior Anti-Cancer Systemic Therapy, n (%)	2 (15.4)	5 (29.4)	7 (23.3)
Platinum Based Prior Anti-Cancer Systemic Therapy			
Yes	2 (15.4)	5 (29.4)	7 (23.3)
No	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Treatment Setting of Prior Anti-Cancer Systemic Therapies, n (%) [a]			
Neo-adjuvant Setting	2 (15.4)	4 (23.5)	6 (20.0)
Adjuvant Setting	1 (7.7)	0 (0.0)	1 (3.3)
In Combination with Definitive Radiotherapy	0 (0.0)	2 (11.8)	2 (6.7)
Duration of Last Prior Anti-Cancer Systemic Therapy (months)			
n	2	5	7
Mean (SD)	1.81 (1.254)	2.24 (1.291)	2.12 (1.191)
Median	1.81	1.81	1.81
Q1, Q3	0.92, 2.69	1.58, 2.50	0.99, 2.69
Min, Max	0.9, 2.7	1.0, 4.3	0.9, 4.3

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

[a] A patient was counted only once within each category but may be counted in multiple categories.

[b] Study Entry date referred to randomization date in this study.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Radiotherapy, n (%)	1 (7.7)	3 (17.6)	4 (13.3)
Site Irradiated, n (%) [a]			
Brain	0 (0.0)	1 (5.9)	1 (3.3)
Lung - left	0 (0.0)	0 (0.0)	0 (0.0)
Lung - right	0 (0.0)	0 (0.0)	0 (0.0)
Liver	0 (0.0)	0 (0.0)	0 (0.0)
Esophagus	0 (0.0)	1 (5.9)	1 (3.3)
Head and neck	0 (0.0)	0 (0.0)	0 (0.0)
Stomach	0 (0.0)	0 (0.0)	0 (0.0)
Retroperitoneum	1 (7.7)	0 (0.0)	1 (3.3)
Bone	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Anti-Cancer Surgery, n (%)	4 (30.8)	7 (41.2)	11 (36.7)
Surgical Procedure, n (%) [a]			
Esophagectomy - Upper	0 (0.0)	3 (17.6)	3 (10.0)
Esophagectomy - Middle	2 (15.4)	1 (5.9)	3 (10.0)
Esophagectomy - Lower	2 (15.4)	2 (11.8)	4 (13.3)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-pr-crs.sas 21OCT2024 08:35 t-14-1-5-1-pr-crs-pop1-3y.rtf

Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Prior Medication	7 (53.8)	8 (47.1)	15 (50.0)
Amides	2 (15.4)	1 (5.9)	3 (10.0)
Lidocaine	2 (15.4)	1 (5.9)	3 (10.0)
Third-Generation Cephalosporins	2 (15.4)	0 (0.0)	2 (6.7)
Cefditoren Pivoxil	1 (7.7)	0 (0.0)	1 (3.3)
Cefotaxime Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids	1 (7.7)	0 (0.0)	1 (3.3)
Tranexamic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Anesthetics, Local	1 (7.7)	0 (0.0)	1 (3.3)
Dyclonine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Anilides	1 (7.7)	1 (5.9)	2 (6.7)
Paracetamol	1 (7.7)	1 (5.9)	2 (6.7)
Benzodiazepine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Amoxicillin;clavulanic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Contact Laxatives	1 (7.7)	0 (0.0)	1 (3.3)
Sennoside A+b Calcium	1 (7.7)	0 (0.0)	1 (3.3)
Fluoroquinolones	1 (7.7)	0 (0.0)	1 (3.3)
Levofloxacin	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
H2-Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Famotidine	1 (7.7)	0 (0.0)	1 (3.3)
Natural Opium Alkaloids	1 (7.7)	0 (0.0)	1 (3.3)
Hydromorphone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	0 (0.0)	1 (3.3)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	0 (0.0)	1 (3.3)
Aldioxa	1 (7.7)	0 (0.0)	1 (3.3)
Proton Pump Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Esomeprazole Sodium	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	1 (7.7)	2 (11.8)	3 (10.0)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Unspecified Herbal And Traditional Medicine	1 (7.7)	0 (0.0)	1 (3.3)
Ginkgo Biloba Extract	1 (7.7)	0 (0.0)	1 (3.3)
Vitamin B1, Plain	1 (7.7)	0 (0.0)	1 (3.3)
Cetotiamine	1 (7.7)	0 (0.0)	1 (3.3)
Acetic Acid Derivatives And Related Substances	0 (0.0)	2 (11.8)	2 (6.7)
Aceclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Ketorolac Tromethamine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	0 (0.0)	1 (5.9)	1 (3.3)
Candesartan	0 (0.0)	1 (5.9)	1 (3.3)
Dihydropyridine Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)
Electrolyte Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Magnesium Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	0 (0.0)	1 (5.9)	1 (3.3)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefazolin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	0 (0.0)	2 (11.8)	2 (6.7)
Dexamethasone Sodium Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Triamcinolone	0 (0.0)	1 (5.9)	1 (3.3)
Opioid Anesthetics	0 (0.0)	1 (5.9)	1 (3.3)
Fentanyl Citrate	0 (0.0)	1 (5.9)	1 (3.3)
Other Opioids	0 (0.0)	1 (5.9)	1 (3.3)
Tramadol Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccines	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccine Conj 13v (Crm197)	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions For Parenteral Nutrition	0 (0.0)	2 (11.8)	2 (6.7)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Medication	13 (100.0)	17 (100.0)	30 (100.0)
Serotonin (5ht3) Antagonists	12 (92.3)	15 (88.2)	27 (90.0)
Palonosetron Hydrochloride	5 (38.5)	8 (47.1)	13 (43.3)
Granisetron	3 (23.1)	2 (11.8)	5 (16.7)
Ondansetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Tropisetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Netupitant;palonosetron	1 (7.7)	0 (0.0)	1 (3.3)
Ondansetron	1 (7.7)	5 (29.4)	6 (20.0)
Palonosetron	1 (7.7)	0 (0.0)	1 (3.3)
Tropisetron	1 (7.7)	1 (5.9)	2 (6.7)
Granisetron Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Sulfonamides, Plain	11 (84.6)	8 (47.1)	19 (63.3)
Furosemide	9 (69.2)	8 (47.1)	17 (56.7)
Torasemide	2 (15.4)	0 (0.0)	2 (6.7)
Indapamide	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	1 (5.9)	2 (6.7)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Osmotically Acting Laxatives	9 (69.2)	8 (47.1)	17 (56.7)
Magnesium Oxide	6 (46.2)	6 (35.3)	12 (40.0)
Lactulose	2 (15.4)	1 (5.9)	3 (10.0)
Macrogol	1 (7.7)	0 (0.0)	1 (3.3)
Magnesium Hydroxide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antiemetics	9 (69.2)	13 (76.5)	22 (73.3)
Aprepitant	7 (53.8)	6 (35.3)	13 (43.3)
Fosaprepitant Meglumine	2 (15.4)	8 (47.1)	10 (33.3)
Prochlorperazine	1 (7.7)	1 (5.9)	2 (6.7)
Promethazine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine Hydrochloride;diprophylline	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)
Prochlorperazine Maleate	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Electrolyte Solutions	8 (61.5)	13 (76.5)	21 (70.0)
Potassium Chloride	6 (46.2)	5 (29.4)	11 (36.7)
Magnesium Sulfate	4 (30.8)	8 (47.1)	12 (40.0)
Calcium Chloride;potassium Chloride;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Electrolyte Solutions [umbrella Term]	0 (0.0)	1 (5.9)	1 (3.3)
Potassium	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Phosphate	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-3y.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Proton Pump Inhibitors	8 (61.5)	12 (70.6)	20 (66.7)
Omeprazole	4 (30.8)	1 (5.9)	5 (16.7)
Esomeprazole Sodium	2 (15.4)	0 (0.0)	2 (6.7)
Lansoprazole	2 (15.4)	2 (11.8)	4 (13.3)
Esomeprazole	1 (7.7)	2 (11.8)	3 (10.0)
Esomeprazole Magnesium	1 (7.7)	0 (0.0)	1 (3.3)
Pantoprazole	1 (7.7)	0 (0.0)	1 (3.3)
Dexlansoprazole	0 (0.0)	1 (5.9)	1 (3.3)
Omeprazole Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Pantoprazole Sodium Sesquihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Rabeprazole Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Vonoprazan Fumarate	0 (0.0)	3 (17.6)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	7 (53.8)	12 (70.6)	19 (63.3)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	3 (17.6)	5 (16.7)
Electrolytes Nos;glucose	2 (15.4)	1 (5.9)	3 (10.0)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	0 (0.0)	2 (6.7)
Sodium Chloride	2 (15.4)	7 (41.2)	9 (30.0)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Gluconate Monohydrate;glucose;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate;sodium Chloride;sodium Citrate Dihydrate	1 (7.7)	1 (5.9)	2 (6.7)
Glucose;sodium Chloride	1 (7.7)	2 (11.8)	3 (10.0)
Solutions Affecting The Electrolyte Balance	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Chloride;sodium Lactate	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride;magnesium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;potassium Chloride;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;sodium Chloride;sodium Lactate	0 (0.0)	4 (23.5)	4 (13.3)
H2-Receptor Antagonists	6 (46.2)	2 (11.8)	8 (26.7)
Famotidine	3 (23.1)	1 (5.9)	4 (13.3)
Cimetidine	2 (15.4)	0 (0.0)	2 (6.7)
Lafutidine	1 (7.7)	0 (0.0)	1 (3.3)
Ranitidine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Propulsives	6 (46.2)	6 (35.3)	12 (40.0)
Metoclopramide Dihydrochloride	3 (23.1)	1 (5.9)	4 (13.3)
Domperidone	1 (7.7)	2 (11.8)	3 (10.0)
Metoclopramide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Mosapride Citrate	1 (7.7)	1 (5.9)	2 (6.7)
Alizapride	0 (0.0)	1 (5.9)	1 (3.3)
Antiemetics And Antinauseants	5 (38.5)	10 (58.8)	15 (50.0)
Metoclopramide	4 (30.8)	5 (29.4)	9 (30.0)
Metoclopramide Hydrochloride	1 (7.7)	5 (29.4)	6 (20.0)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Colony Stimulating Factors	5 (38.5)	2 (11.8)	7 (23.3)
Filgrastim	3 (23.1)	1 (5.9)	4 (13.3)
Peg Granulocyte Colony Stimulating Factor	2 (15.4)	0 (0.0)	2 (6.7)
Mecapegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Pegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Granulocyte Colony Stimulating Factor	0 (0.0)	1 (5.9)	1 (3.3)
Solutions Producing Osmotic Diuresis	5 (38.5)	7 (41.2)	12 (40.0)
Mannitol	5 (38.5)	7 (41.2)	12 (40.0)
Anilides	4 (30.8)	9 (52.9)	13 (43.3)
Paracetamol	4 (30.8)	9 (52.9)	13 (43.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Blood Substitutes And Perfusion Solutions	4 (30.8)	4 (23.5)	8 (26.7)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	4 (30.8)	4 (23.5)	8 (26.7)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	4 (30.8)	2 (11.8)	6 (20.0)
Amoxicillin;clavulanic Acid	2 (15.4)	0 (0.0)	2 (6.7)
Amoxicillin Trihydrate;clavulanate Potassium	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Ampicillin Sodium;sulbactam Sodium	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Contact Laxatives	4 (30.8)	8 (47.1)	12 (40.0)
Sennoside A+b	3 (23.1)	6 (35.3)	9 (30.0)
Bisacodyl	1 (7.7)	3 (17.6)	4 (13.3)
Sennoside A+b Calcium	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Picosulfate	1 (7.7)	4 (23.5)	5 (16.7)
Senna Alexandrina Extract	0 (0.0)	1 (5.9)	1 (3.3)
Fluoroquinolones	4 (30.8)	2 (11.8)	6 (20.0)
Levofloxacin	3 (23.1)	1 (5.9)	4 (13.3)
Ciprofloxacin	1 (7.7)	0 (0.0)	1 (3.3)
Ofloxacin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Heparin Group	4 (30.8)	3 (17.6)	7 (23.3)
Heparin Calcium	2 (15.4)	0 (0.0)	2 (6.7)
Bemiparin	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin	0 (0.0)	1 (5.9)	1 (3.3)
Heparin Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Corticosteroids, Potent (Group Iii)	3 (23.1)	1 (5.9)	4 (13.3)
Betamethasone Butyrate Propionate	1 (7.7)	0 (0.0)	1 (3.3)
Halometasone	1 (7.7)	0 (0.0)	1 (3.3)
Mometasone Furoate	1 (7.7)	0 (0.0)	1 (3.3)
Betamethasone Valerate	0 (0.0)	1 (5.9)	1 (3.3)
Difluprednate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Dihydropyridine Derivatives	3 (23.1)	3 (17.6)	6 (20.0)
Cilnidipine	2 (15.4)	0 (0.0)	2 (6.7)
Amlodipine	1 (7.7)	2 (11.8)	3 (10.0)
Lercanidipine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)
Imidazole And Triazole Derivatives	3 (23.1)	1 (5.9)	4 (13.3)
Clobetasol Propionate;ketoconazole	1 (7.7)	0 (0.0)	1 (3.3)
Clotrimazole	1 (7.7)	0 (0.0)	1 (3.3)
Econazole Nitrate	1 (7.7)	0 (0.0)	1 (3.3)
Lanoconazole	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Mucolytics	3 (23.1)	3 (17.6)	6 (20.0)
Acetylcysteine	2 (15.4)	0 (0.0)	2 (6.7)
Ambroxol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Bromhexine Hydrochloride	0 (0.0)	2 (11.8)	2 (6.7)
Carbocisteine	0 (0.0)	1 (5.9)	1 (3.3)
Other Plain Vitamin Preparations	3 (23.1)	1 (5.9)	4 (13.3)
Pyridoxine Hydrochloride	3 (23.1)	1 (5.9)	4 (13.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Potassium	3 (23.1)	2 (11.8)	5 (16.7)
Potassium Chloride	2 (15.4)	0 (0.0)	2 (6.7)
Potassium Aspartate	1 (7.7)	2 (11.8)	3 (10.0)
Potassium Gluconate	0 (0.0)	1 (5.9)	1 (3.3)
Solutions For Parenteral Nutrition	3 (23.1)	6 (35.3)	9 (30.0)
Amino Acids Nos;fats Nos;glucose	2 (15.4)	0 (0.0)	2 (6.7)
Dl-Alpha Tocopheryl Acetate;glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	2 (15.4)	0 (0.0)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-3y.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetic Acid;alanine;arginine;aspartic Acid;calcium;calcium Chloride;chloride;glucose;glutamate Sodium;glycerol;glycine;glycine Max Seed Oil;histidine;isoleucine;lecithin;leucine;lysine Hydrochloride;magnesium;magnesium Sulfate;methionine;phenylalanine;phosphorus;potassium;potassium Chloride;proline;serine;sodium;sodium Acetate;sodium Glycerophosphate;sodium Hydroxide;threonine;tryptophan, L-;tyrosine;valine	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Glucose	1 (7.7)	2 (11.8)	3 (10.0)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-3y.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)
Alanine;arginine;aspartic Acid;calcium Chloride;glucose Monohydrate;glutamic Acid;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate;methionine;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	0 (0.0)	2 (11.8)	2 (6.7)
Substituted Alkylamines	3 (23.1)	3 (17.6)	6 (20.0)
Dexchlorpheniramine Maleate	2 (15.4)	2 (11.8)	4 (13.3)
Chlorphenamine	1 (7.7)	0 (0.0)	1 (3.3)
Chlorphenamine Maleate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Unspecified Herbal And Traditional Medicine	3 (23.1)	5 (29.4)	8 (26.7)
Unspecified Herbal And Traditional Medicine	2 (15.4)	0 (0.0)	2 (6.7)
Angelica Sinensis Root;atractylodes Macrocephala, Rhizoma;cremastra Appendiculata Pseudobulb;epimedium Spp.;panax Ginseng Root;solanum Lyratum;sophora Flavescens Root	1 (7.7)	0 (0.0)	1 (3.3)
Animal Unspecified;borneol;cow Bezoar;fungi Nos;indigo;pearl	1 (7.7)	0 (0.0)	1 (3.3)
Angelica Dahurica Root;calcium Sulfate Dihydrate;chrysanthemum X Morifolium Flower;coptis Chinensis Rhizome;forsythia Suspensa Fruit;gardenia Jasminoides Fruit;glycyrrhiza Spp. Root With Rhizome;inula Japonica Inflorescence;ligusticum Chuanxiong Rhizome;mentha Canadensis Herb;phellodendron Chinense Bark;platycodon Grandiflorus Root;rheum Spp. Root With Rhizome;saposhnikovia Divaricata Root;schizonepeta Tenuifolia Spike;scutellaria Baicalensis Root;vitex Trifolia Fruit	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	0 (0.0)	1 (5.9)	1 (3.3)
Citrus Aurantium Pericarp;creosote;glycyrrhiza Spp. Root With Rhizome;phellodendron Spp. Stem Bark;senegalia Catechu Twig	0 (0.0)	1 (5.9)	1 (3.3)
Coptis Spp.;glycyrrhiza Spp.;panax Ginseng;pinellia Ternata;scutellaria Baicalensis;zingiber Officinale;ziziphus Jujuba	0 (0.0)	1 (5.9)	1 (3.3)
Glycine Max Seed Oil	0 (0.0)	1 (5.9)	1 (3.3)
Glycyrrhiza Spp. Root;paeonia Lactiflora Root	0 (0.0)	2 (11.8)	2 (6.7)
Isatis Tinctoria Root;lobelia Chinensis Herb;taraxacum Spp. Herb;viola Philippica Herb	0 (0.0)	1 (5.9)	1 (3.3)
Panax Ginseng Root;zanthoxylum Piperitum Pericarp;zingiber Officinale Processed Rhizome	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antiinfectives And Antiseptics For Local Oral Treatment	2 (15.4)	1 (5.9)	3 (10.0)
Chlorhexidine	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Antiinfectives And Antiseptics For Local Oral Treatment	0 (0.0)	1 (5.9)	1 (3.3)
Ascorbic Acid (Vitamin C), Plain	2 (15.4)	1 (5.9)	3 (10.0)
Ascorbic Acid	2 (15.4)	1 (5.9)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-3y.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Brotizolam	1 (7.7)	2 (11.8)	3 (10.0)
Estazolam	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Midazolam	1 (7.7)	1 (5.9)	2 (6.7)
Alprazolam	0 (0.0)	3 (17.6)	3 (10.0)
Flunitrazepam	0 (0.0)	1 (5.9)	1 (3.3)
Phenazepam	0 (0.0)	1 (5.9)	1 (3.3)
Biguanides	2 (15.4)	2 (11.8)	4 (13.3)
Metformin	1 (7.7)	0 (0.0)	1 (3.3)
Metformin Hydrochloride	1 (7.7)	2 (11.8)	3 (10.0)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Vitamins	2 (15.4)	0 (0.0)	2 (6.7)
Combinations Of Vitamins	1 (7.7)	0 (0.0)	1 (3.3)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)
Corticosteroids For Local Oral Treatment	2 (15.4)	2 (11.8)	4 (13.3)
Dexamethasone	2 (15.4)	2 (11.8)	4 (13.3)
Triamcinolone	1 (7.7)	0 (0.0)	1 (3.3)
General Nutrients	2 (15.4)	2 (11.8)	4 (13.3)
General Nutrients	1 (7.7)	2 (11.8)	3 (10.0)
Nutrients Nos	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Insulins And Analogues For Injection, Fast-Acting	2 (15.4)	3 (17.6)	5 (16.7)
Insulin	2 (15.4)	1 (5.9)	3 (10.0)
Insulin Human	0 (0.0)	1 (5.9)	1 (3.3)
Insulin Lispro	0 (0.0)	1 (5.9)	1 (3.3)
Macrolides	2 (15.4)	0 (0.0)	2 (6.7)
Roxithromycin	2 (15.4)	0 (0.0)	2 (6.7)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	2 (15.4)	0 (0.0)	2 (6.7)
Entecavir	2 (15.4)	0 (0.0)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Opium Alkaloids And Derivatives	2 (15.4)	1 (5.9)	3 (10.0)
Dextromethorphan	1 (7.7)	0 (0.0)	1 (3.3)
Dextromethorphan Hydrobromide	1 (7.7)	1 (5.9)	2 (6.7)
Other Antihistamines For Systemic Use	2 (15.4)	1 (5.9)	3 (10.0)
Cyproheptadine	1 (7.7)	0 (0.0)	1 (3.3)
Ebastine	1 (7.7)	0 (0.0)	1 (3.3)
Mebhydrolin	1 (7.7)	0 (0.0)	1 (3.3)
Rupatadine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-3y.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs For Constipation	2 (15.4)	2 (11.8)	4 (13.3)
Glycerol	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	1 (7.7)	2 (11.8)	3 (10.0)
Linaclotide	0 (0.0)	1 (5.9)	1 (3.3)
Other Immunostimulants	2 (15.4)	1 (5.9)	3 (10.0)
Batilol	1 (7.7)	1 (5.9)	2 (6.7)
Leucogen	1 (7.7)	0 (0.0)	1 (3.3)
Penicillins With Extended Spectrum	2 (15.4)	1 (5.9)	3 (10.0)
Amoxicillin	2 (15.4)	0 (0.0)	2 (6.7)
Amoxicillin Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Preparations Inhibiting Uric Acid Production	2 (15.4)	3 (17.6)	5 (16.7)
Allopurinol	1 (7.7)	1 (5.9)	2 (6.7)
Febuxostat	1 (7.7)	3 (17.6)	4 (13.3)
Propionic Acid Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Dexketoprofen	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen	1 (7.7)	1 (5.9)	2 (6.7)
Loxoprofen Sodium	1 (7.7)	3 (17.6)	4 (13.3)
Flurbiprofen Axetil	0 (0.0)	1 (5.9)	1 (3.3)
Loxoprofen Sodium Dihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Zaltoprofen	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetic Acid Derivatives And Related Substances	1 (7.7)	0 (0.0)	1 (3.3)
Diclofenac Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	1 (7.7)	0 (0.0)	1 (3.3)
Fluticasone Furoate;vilanterol Trifenatate	1 (7.7)	0 (0.0)	1 (3.3)
Alpha-Adrenoreceptor Antagonists	1 (7.7)	1 (5.9)	2 (6.7)
Silodosin	1 (7.7)	1 (5.9)	2 (6.7)
Amides	1 (7.7)	1 (5.9)	2 (6.7)
Lidocaine	1 (7.7)	0 (0.0)	1 (3.3)
Lidocaine Hydrochloride;prilocaine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Aminoalkyl Ethers	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine	1 (7.7)	0 (0.0)	1 (3.3)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	1 (7.7)	1 (5.9)	2 (6.7)
Cilnidipine;valsartan	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate;telmisartan	0 (0.0)	1 (5.9)	1 (3.3)
Antibacterials For Systemic Use	1 (7.7)	0 (0.0)	1 (3.3)
Antibiotics	1 (7.7)	0 (0.0)	1 (3.3)
Antibiotics	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Rifampicin	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antidotes	1 (7.7)	1 (5.9)	2 (6.7)
Glutathione	1 (7.7)	1 (5.9)	2 (6.7)
Antiinflammatory Preparations, Non-Steroids For Topical Use	1 (7.7)	1 (5.9)	2 (6.7)
Felbinac	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Antipropulsives	1 (7.7)	1 (5.9)	2 (6.7)
Loperamide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Appetite Stimulants	1 (7.7)	0 (0.0)	1 (3.3)
Megestrol	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Related Drugs	1 (7.7)	3 (17.6)	4 (13.3)
Zolpidem	1 (7.7)	0 (0.0)	1 (3.3)
Eszopiclone	0 (0.0)	2 (11.8)	2 (6.7)
Zolpidem Tartrate	0 (0.0)	2 (11.8)	2 (6.7)
Benzomorphan Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Pentazocine	1 (7.7)	0 (0.0)	1 (3.3)
Beta Blocking Agents, Non-Selective	1 (7.7)	0 (0.0)	1 (3.3)
Propranolol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Beta Blocking Agents, Selective	1 (7.7)	2 (11.8)	3 (10.0)
Atenolol	1 (7.7)	0 (0.0)	1 (3.3)
Bisoprolol	1 (7.7)	1 (5.9)	2 (6.7)
Bisoprolol Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Calcium, Combinations With Vitamin D And/Or Other Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Carbonate;colecalciferol;magnesium Carbonate	1 (7.7)	0 (0.0)	1 (3.3)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	1 (7.7)	0 (0.0)	1 (3.3)
Almagate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid;rifampicin	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Various Lipid Modifying Agents	1 (7.7)	0 (0.0)	1 (3.3)
Atorvastatin;ezetimibe	1 (7.7)	0 (0.0)	1 (3.3)
Corticosteroids, Very Potent (Group Iv)	1 (7.7)	1 (5.9)	2 (6.7)
Clobetasol Propionate	1 (7.7)	1 (5.9)	2 (6.7)
Corticosteroids, Weak (Group I)	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Coxibs	1 (7.7)	1 (5.9)	2 (6.7)
Etoricoxib	1 (7.7)	0 (0.0)	1 (3.3)
Celecoxib	0 (0.0)	1 (5.9)	1 (3.3)
Diazepines, Oxazepines, Thiazepines And Oxepines	1 (7.7)	4 (23.5)	5 (16.7)
Quetiapine	1 (7.7)	0 (0.0)	1 (3.3)
Olanzapine	0 (0.0)	4 (23.5)	4 (13.3)
Quetiapine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Enemas	1 (7.7)	0 (0.0)	1 (3.3)
Glycerol	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Enzymes	1 (7.7)	1 (5.9)	2 (6.7)
Bromelains;cysteine	1 (7.7)	0 (0.0)	1 (3.3)
Pronase;sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	1 (7.7)	4 (23.5)	5 (16.7)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	1 (7.7)	2 (11.8)	3 (10.0)
Carbohydrates Nos;electrolytes Nos;lipids Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
Fibrates	1 (7.7)	0 (0.0)	1 (3.3)
Bezafibrate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Heparins Or Heparinoids For Topical Use	1 (7.7)	0 (0.0)	1 (3.3)
Mucopolysaccharide Polysulfuric Acid Ester	1 (7.7)	0 (0.0)	1 (3.3)
Hmg Coa Reductase Inhibitors	1 (7.7)	3 (17.6)	4 (13.3)
Pravastatin	1 (7.7)	1 (5.9)	2 (6.7)
Simvastatin	1 (7.7)	1 (5.9)	2 (6.7)
Rosuvastatin	0 (0.0)	1 (5.9)	1 (3.3)
Hydrazides	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	1 (7.7)	1 (5.9)	2 (6.7)
Insulin Human;insulin Human Injection, Isophane	1 (7.7)	0 (0.0)	1 (3.3)
Insulin Aspart;insulin Aspart Protamine (Crystalline)	0 (0.0)	1 (5.9)	1 (3.3)
Leukotriene Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Montelukast	1 (7.7)	0 (0.0)	1 (3.3)
Medical Gases	1 (7.7)	0 (0.0)	1 (3.3)
Oxygen	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Natural Opium Alkaloids	1 (7.7)	6 (35.3)	7 (23.3)
Codeine	1 (7.7)	0 (0.0)	1 (3.3)
Codeine Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Hydromorphone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Naloxone Hydrochloride;oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Agents For Local Oral Treatment	1 (7.7)	6 (35.3)	7 (23.3)
Sodium Gualenate Hydrate	1 (7.7)	3 (17.6)	4 (13.3)
Benzydamine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Diclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Glycerol	0 (0.0)	1 (5.9)	1 (3.3)
Lidocaine	0 (0.0)	2 (11.8)	2 (6.7)
Other Analgesics And Antipyretics	1 (7.7)	1 (5.9)	2 (6.7)
Pregabalin	1 (7.7)	1 (5.9)	2 (6.7)
Other Antibiotics For Topical Use	1 (7.7)	2 (11.8)	3 (10.0)
Mupirocin	1 (7.7)	1 (5.9)	2 (6.7)
Gentamicin Sulfate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antidepressants	1 (7.7)	2 (11.8)	3 (10.0)
Mianserin	1 (7.7)	0 (0.0)	1 (3.3)
Trazodone	0 (0.0)	1 (5.9)	1 (3.3)
Trazodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Other Antidiarrheals	1 (7.7)	0 (0.0)	1 (3.3)
Racecadotril	1 (7.7)	0 (0.0)	1 (3.3)
Other Blood Glucose Lowering Drugs, Excl. Insulins	1 (7.7)	0 (0.0)	1 (3.3)
Repaglinide	1 (7.7)	0 (0.0)	1 (3.3)
Other Dermatologicals	1 (7.7)	0 (0.0)	1 (3.3)
Camphor;methyl Salicylate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs Affecting Bone Structure And Mineralization	1 (7.7)	0 (0.0)	1 (3.3)
Denosumab	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	1 (5.9)	2 (6.7)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Simeticone	0 (0.0)	1 (5.9)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	1 (5.9)	2 (6.7)
Sucralfate	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Alginate	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Ethambutol	1 (7.7)	0 (0.0)	1 (3.3)
Pyrazinamide	1 (7.7)	0 (0.0)	1 (3.3)
Other Hypnotics And Sedatives	1 (7.7)	2 (11.8)	3 (10.0)
Doxepin Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Suvorexant	0 (0.0)	2 (11.8)	2 (6.7)
Other Intestinal Adsorbents	1 (7.7)	1 (5.9)	2 (6.7)
Montmorillonite	1 (7.7)	0 (0.0)	1 (3.3)
Gelatin Tannate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Nervous System Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Mecobalamin	1 (7.7)	0 (0.0)	1 (3.3)
Other Throat Preparations	1 (7.7)	0 (0.0)	1 (3.3)
Benzydamine	1 (7.7)	0 (0.0)	1 (3.3)
Other Viral Vaccines	1 (7.7)	2 (11.8)	3 (10.0)
Covid-19 Vaccine Mrna (Mrna 1273)	1 (7.7)	0 (0.0)	1 (3.3)
Tozinameran	0 (0.0)	2 (11.8)	2 (6.7)
Phenothiazines With Aliphatic Side-Chain	1 (7.7)	3 (17.6)	4 (13.3)
Chlorpromazine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Chlorpromazine	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Piperazine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Levocetirizine	1 (7.7)	0 (0.0)	1 (3.3)
Platelet Aggregation Inhibitors Excl. Heparin	1 (7.7)	2 (11.8)	3 (10.0)
Acetylsalicylate Lysine	1 (7.7)	1 (5.9)	2 (6.7)
Acetylsalicylic Acid	0 (0.0)	1 (5.9)	1 (3.3)
Pyrazolones	1 (7.7)	0 (0.0)	1 (3.3)
Metamizole	1 (7.7)	0 (0.0)	1 (3.3)
Second-Generation Cephalosporins	1 (7.7)	1 (5.9)	2 (6.7)
Cefaclor	1 (7.7)	0 (0.0)	1 (3.3)
Cefuroxime	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Selective Beta-2-Adrenoreceptor Agonists	1 (7.7)	1 (5.9)	2 (6.7)
Bambuterol	1 (7.7)	0 (0.0)	1 (3.3)
Tulobuterol	0 (0.0)	1 (5.9)	1 (3.3)
Selective Serotonin Reuptake Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Sertraline	1 (7.7)	0 (0.0)	1 (3.3)
Third-Generation Cephalosporins	1 (7.7)	2 (11.8)	3 (10.0)
Ceftriaxone Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Cefcapene Pivoxil Hydrochloride Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Cefoperazone	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Tonics	1 (7.7)	0 (0.0)	1 (3.3)
Inosine;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Vitamins	1 (7.7)	1 (5.9)	2 (6.7)
Ascorbic Acid;biotin;cocarboxylase Tetrahydrate;colecalciferol;cyanocobalamin;dexpanthenol;dl-Alpha Tocopherol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)
Ace Inhibitors, Plain	0 (0.0)	2 (11.8)	2 (6.7)
Perindopril	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids	0 (0.0)	1 (5.9)	1 (3.3)
Fenoterol Hydrobromide;ipratropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)
Aldose Reductase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Epalrestat	0 (0.0)	1 (5.9)	1 (3.3)
Aldosterone Antagonists	0 (0.0)	2 (11.8)	2 (6.7)
Spironolactone	0 (0.0)	2 (11.8)	2 (6.7)
Alpha Glucosidase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Voglibose	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Amino Acids And Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Ademetionine	0 (0.0)	1 (5.9)	1 (3.3)
Antidiarrheal Microorganisms	0 (0.0)	3 (17.6)	3 (10.0)
Antidiarrheal Microorganisms	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Subtilis;lactomin	0 (0.0)	1 (5.9)	1 (3.3)
Antiseptics	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate;sodium Gualenate Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	0 (0.0)	1 (5.9)	1 (3.3)
Cimetropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzamides	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)
Beta Blocking Agents	0 (0.0)	1 (5.9)	1 (3.3)
Timolol	0 (0.0)	1 (5.9)	1 (3.3)
Bioflavonoids	0 (0.0)	1 (5.9)	1 (3.3)
Diosmin;hesperidin	0 (0.0)	1 (5.9)	1 (3.3)
Bisphosphonates	0 (0.0)	1 (5.9)	1 (3.3)
Zoledronic Acid	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Butyrophenone Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Haloperidol	0 (0.0)	2 (11.8)	2 (6.7)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Carbamide Products	0 (0.0)	1 (5.9)	1 (3.3)
Urea	0 (0.0)	1 (5.9)	1 (3.3)
Carbapenems	0 (0.0)	2 (11.8)	2 (6.7)
Meropenem	0 (0.0)	1 (5.9)	1 (3.3)
Meropenem Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-3y.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Oral Blood Glucose Lowering Drugs	0 (0.0)	1 (5.9)	1 (3.3)
Metformin Hydrochloride;sitagliptin Phosphate Monohydrate	0 (0.0)	1 (5.9)	1 (3.3)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	0 (0.0)	4 (23.5)	4 (13.3)
Linagliptin	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate Monohydrate	0 (0.0)	2 (11.8)	2 (6.7)
Diphenylmethane Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Direct Factor Xa Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Apixaban	0 (0.0)	1 (5.9)	1 (3.3)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefradine	0 (0.0)	1 (5.9)	1 (3.3)
Insulins And Analogues For Injection, Long-Acting	0 (0.0)	1 (5.9)	1 (3.3)
Insulin Glargine Biosimilar 1	0 (0.0)	1 (5.9)	1 (3.3)
Iron Trivalent, Oral Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Ferric Pyrophosphate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm.sas 21OCT2024 08:30 t-14-1-7-1-cm-gen-pop1-3y.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Iron, Parenteral Preparations	0 (0.0)	2 (11.8)	2 (6.7)
Saccharated Iron Oxide	0 (0.0)	2 (11.8)	2 (6.7)
Liver Therapy	0 (0.0)	2 (11.8)	2 (6.7)
Cysteine Hydrochloride;glycine;glycyrrhizic Acid, Ammonium Salt	0 (0.0)	1 (5.9)	1 (3.3)
Ornithine Aspartate	0 (0.0)	1 (5.9)	1 (3.3)
Polyene Phosphatidylcholine	0 (0.0)	1 (5.9)	1 (3.3)
Melatonin Receptor Agonists	0 (0.0)	1 (5.9)	1 (3.3)
Ramelteon	0 (0.0)	1 (5.9)	1 (3.3)
Other Aminoglycosides	0 (0.0)	1 (5.9)	1 (3.3)
Amikacin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antianemic Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Darbepoetin Alfa	0 (0.0)	1 (5.9)	1 (3.3)
Other Antibacterials	0 (0.0)	1 (5.9)	1 (3.3)
Fosfomycin	0 (0.0)	1 (5.9)	1 (3.3)
Other Antiepileptics	0 (0.0)	1 (5.9)	1 (3.3)
Lacosamide	0 (0.0)	1 (5.9)	1 (3.3)
Levetiracetam	0 (0.0)	1 (5.9)	1 (3.3)
Other Antimigraine Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Flunarizine Dihydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antipruritics	0 (0.0)	1 (5.9)	1 (3.3)
Crotamiton	0 (0.0)	1 (5.9)	1 (3.3)
Other Blood Products	0 (0.0)	1 (5.9)	1 (3.3)
Blood, Whole	0 (0.0)	1 (5.9)	1 (3.3)
Other Centrally Acting Agents	0 (0.0)	1 (5.9)	1 (3.3)
Baclofen	0 (0.0)	1 (5.9)	1 (3.3)
Other Emollients And Protectives	0 (0.0)	2 (11.8)	2 (6.7)
Mucopolysaccharide Polysulfuric Acid Ester	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Irrigating Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Mannitol;sorbitol	0 (0.0)	1 (5.9)	1 (3.3)
Peripheral Opioid Receptor Antagonists	0 (0.0)	1 (5.9)	1 (3.3)
Naldemedine Tosilate	0 (0.0)	1 (5.9)	1 (3.3)
Phenylpiperidine Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Fentanyl Citrate	0 (0.0)	2 (11.8)	2 (6.7)
Preparations Increasing Uric Acid Excretion	0 (0.0)	1 (5.9)	1 (3.3)
Benzbromarone	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Preparations With No Effect On Uric Acid Metabolism	0 (0.0)	1 (5.9)	1 (3.3)
Colchicine	0 (0.0)	1 (5.9)	1 (3.3)
Proteinase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Camostat Mesilate	0 (0.0)	1 (5.9)	1 (3.3)
Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic (Monohydrate)	0 (0.0)	1 (5.9)	1 (3.3)
Soft Paraffin And Fat Products	0 (0.0)	1 (5.9)	1 (3.3)
White Soft Paraffin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Stomatological Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)
Sulfonylureas	0 (0.0)	1 (5.9)	1 (3.3)
Gliclazide	0 (0.0)	1 (5.9)	1 (3.3)
Triazole Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Fluconazole	0 (0.0)	1 (5.9)	1 (3.3)
Various Alimentary Tract And Metabolism Products	0 (0.0)	2 (11.8)	2 (6.7)
Borneol;cow Bezoar;musk;pearl;potassium Nitrate;realgar;sodium Borate Decahydrate;zingiber Officinale Rhizome	0 (0.0)	1 (5.9)	1 (3.3)
Zinc Acetate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Disulfide	0 (0.0)	2 (11.8)	2 (6.7)
Vitamin B12 (Cyanocobalamin And Analogues)	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin B12 Nos	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D And Analogues	0 (0.0)	2 (11.8)	2 (6.7)
Colecalciferol	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D Nos	0 (0.0)	1 (5.9)	1 (3.3)
Xanthines	0 (0.0)	1 (5.9)	1 (3.3)
Theophylline	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Systemically Administered Corticosteroids/Immunosuppressive Drug During the Study	10 (76.9)	14 (82.4)	24 (80.0)
Patients with at Least One Concomitant Systemically Administered Corticosteroids Drugs	10 (76.9)	14 (82.4)	24 (80.0)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-cm1.sas 21OCT2024 08:30 t-14-1-7-2-cm1-cor-pop1-3y.rtf

Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	1 (5.9)	2 (6.7)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Immunosuppressive Drugs	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Overall Survival [a]			
n	13	17	30
Mean (SD)	29.87 (16.227)	17.59 (15.570)	22.91 (16.763)
Median	26.48	9.76	19.83
Q1, Q3	19.12, 44.22	6.97, 23.82	7.98, 39.36
Min, Max	1.8, 50.9	2.2, 46.1	1.8, 50.9
Progression-Free Survival [b]			
n	13	17	30
Mean (SD)	15.80 (18.227)	8.74 (11.786)	11.80 (15.060)
Median	5.68	4.44	5.52
Q1, Q3	2.83, 29.08	2.07, 8.54	2.76, 9.95
Min, Max	1.8, 48.8	1.2, 46.1	1.2, 48.8

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Investigator Tumor Assessment [c]			
n	13	17	30
Mean (SD)	15.85 (18.193)	8.64 (10.945)	11.77 (14.706)
Median	5.68	4.44	5.60
Q1, Q3	4.04, 29.08	2.66, 8.54	2.76, 9.95
Min, Max	1.3, 48.8	1.2, 42.1	1.2, 48.8
EORTC-QLQ-C30 [d]			
n	13	17	30
Mean (SD)	10.75 (14.325)	8.09 (9.253)	9.25 (11.573)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 50.4	1.0, 32.9	0.0, 50.4

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
EORTC-QLQ-OES18 [d]			
n	13	17	30
Mean (SD)	10.75 (14.325)	8.09 (9.253)	9.25 (11.573)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 50.4	1.0, 32.9	0.0, 50.4
EQ-5D VAS [d]			
n	13	17	30
Mean (SD)	10.75 (14.325)	8.09 (9.253)	9.25 (11.573)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 50.4	1.0, 32.9	0.0, 50.4

Source: ADSL, ADTTE, ADEFPRE, ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.2:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Safety for TEAEs [a]			
n	13	17	30
Mean (SD)	13.39 (15.324)	8.12 (9.018)	10.41 (12.210)
Median	5.98	4.63	5.52
Q1, Q3	2.99, 24.44	2.17, 8.80	2.83, 10.28
Min, Max	1.2, 50.9	1.2, 32.9	1.2, 50.9
Safety for imAEs [b]			
n	13	17	30
Mean (SD)	15.20 (14.970)	9.80 (9.227)	12.14 (12.129)
Median	7.95	6.60	7.31
Q1, Q3	5.22, 26.41	3.94, 11.53	4.17, 12.71
Min, Max	1.8, 50.9	2.1, 34.9	1.8, 50.9

Source: ADSL, ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event; imAE, immune-mediated adverse event.

[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.

[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Number of Patients		
Death, n (%)	7 (53.8)	12 (70.6)
Censored, n (%)	6 (46.2)	5 (29.4)
Ongoing Without Events	6 (46.2)	3 (17.6)
Lost to Follow-up	0 (0.0)	1 (5.9)
Withdrawal by Subject	0 (0.0)	1 (5.9)
Two-sided Stratified Log-rank Test p-value [a]	0.4086	
Stratified Hazard Ratio (95% CI) [b]	0.611 (0.189, 1.975)	
Unstratified Hazard Ratio (95% CI) [c]	0.466 (0.181, 1.200)	

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Overall Survival (months)		
Median (95% CI)	26.5 (16.4, NE)	11.8 (7.0, NE)
Q1 (95% CI)	19.1 (1.8, 26.5)	8.0 (2.2, 11.8)
Q3 (95% CI)	NR (26.0, NE)	46.1 (11.8, NE)

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	92.3 (56.6, 98.9)	88.2 (60.6, 96.9)
6 Months (95% CI)	92.3 (56.6, 98.9)	82.4 (54.7, 93.9)
9 Months (95% CI)	84.6 (51.2, 95.9)	69.1 (40.7, 85.9)
12 Months (95% CI)	84.6 (51.2, 95.9)	48.4 (22.5, 70.2)
18 Months (95% CI)	76.9 (44.2, 91.9)	48.4 (22.5, 70.2)
24 Months (95% CI)	61.5 (30.8, 81.8)	27.6 (8.7, 50.9)
30 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)
36 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)
42 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
48 Months (95% CI)	46.2 (19.2, 69.6)	0.0 (NE, NE)
Follow-up Time (months)		
Median (95% CI)	45.4 (39.1, NE)	39.4 (38.3, NE)

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death on or before data cutoff, patients will be censored either at the date that the patient was last known to be alive or the date of data cutoff, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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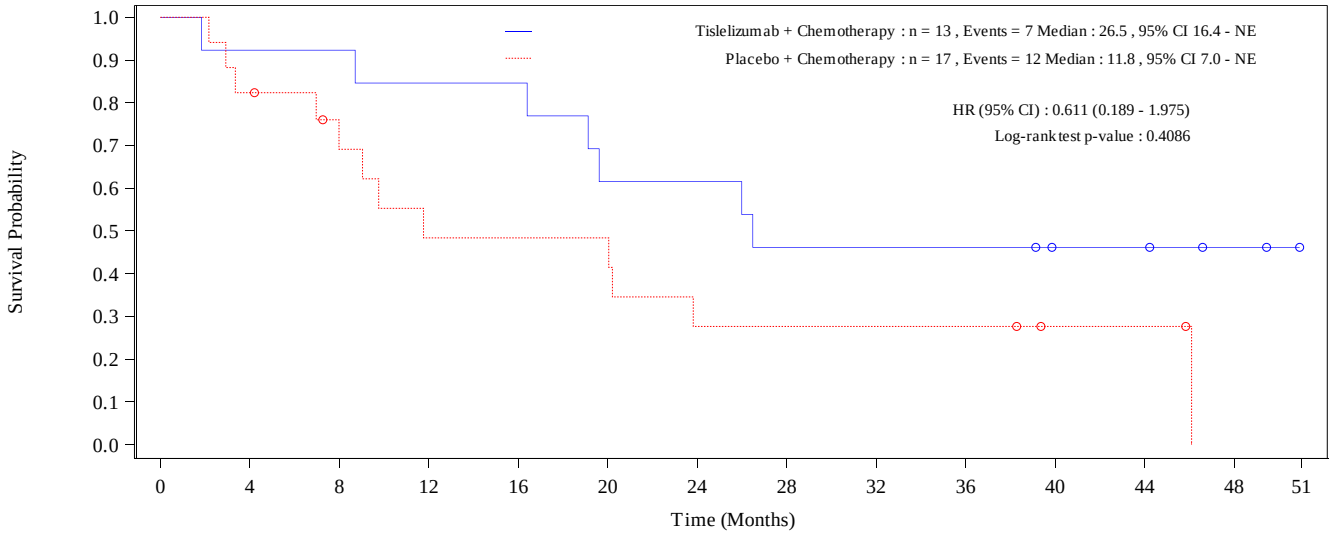
Figure 14.2.1.1:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51
Tislelizumab +Chemotherapy	13	13	12	12	12	12	12	12	12	11	11	11	11	11	11	11	11	11	10	10	10	8	8	8	8	8	8	7	6	6	6	6	6	6	6	6	6	6	6	6	4	4	4	4	4	3	3	2	2	2	1	0
Placebo +Chemotherapy	17	17	17	15	14	13	13	12	10	10	8	8	7	7	7	7	7	7	7	7	7	5	5	5	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	2	2	2	2	2	2	1	0	0	0	0	0

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE, not estimable; NR, not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy. (yes vs no) per IRT.
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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	4 (44.4)	NR (8.7, NE)	8	4 (50.0)	20.0 (3.4, NE)	0.531 (0.131, 2.147)	0.3668
Age >= 65	4	3 (75.0)	26.2 (1.8, NE)	9	8 (88.9)	9.8 (2.2, NE)	0.666 (0.167, 2.663)	0.5631
Interaction								0.7769
Sex								
Male	9	6 (66.7)	26.0 (1.8, NE)	11	8 (72.7)	20.0 (2.9, NE)	0.794 (0.265, 2.380)	0.6798
Female	4	1 (25.0)	NR (19.1, NE)	6	4 (66.7)	9.8 (7.0, NE)	0.192 (0.021, 1.750)	0.1043
Interaction								0.1908

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	19.6 (8.7, 26.5)	10	7 (70.0)	9.8 (2.9, NE)	0.731 (0.243, 2.199)	0.5756
1	6	1 (16.7)	NR (1.8, NE)	7	5 (71.4)	20.2 (2.2, NE)	0.152 (0.017, 1.358)	0.0565
Interaction								0.1283

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	NR (8.7, NE)	7	6 (85.7)	9.8 (2.2, NE)	0.445 (0.089, 2.219)	0.3105
No	9	5 (55.6)	26.5 (1.8, NE)	10	6 (60.0)	20.0 (2.9, NE)	0.535 (0.159, 1.792)	0.3033
Interaction								0.8958

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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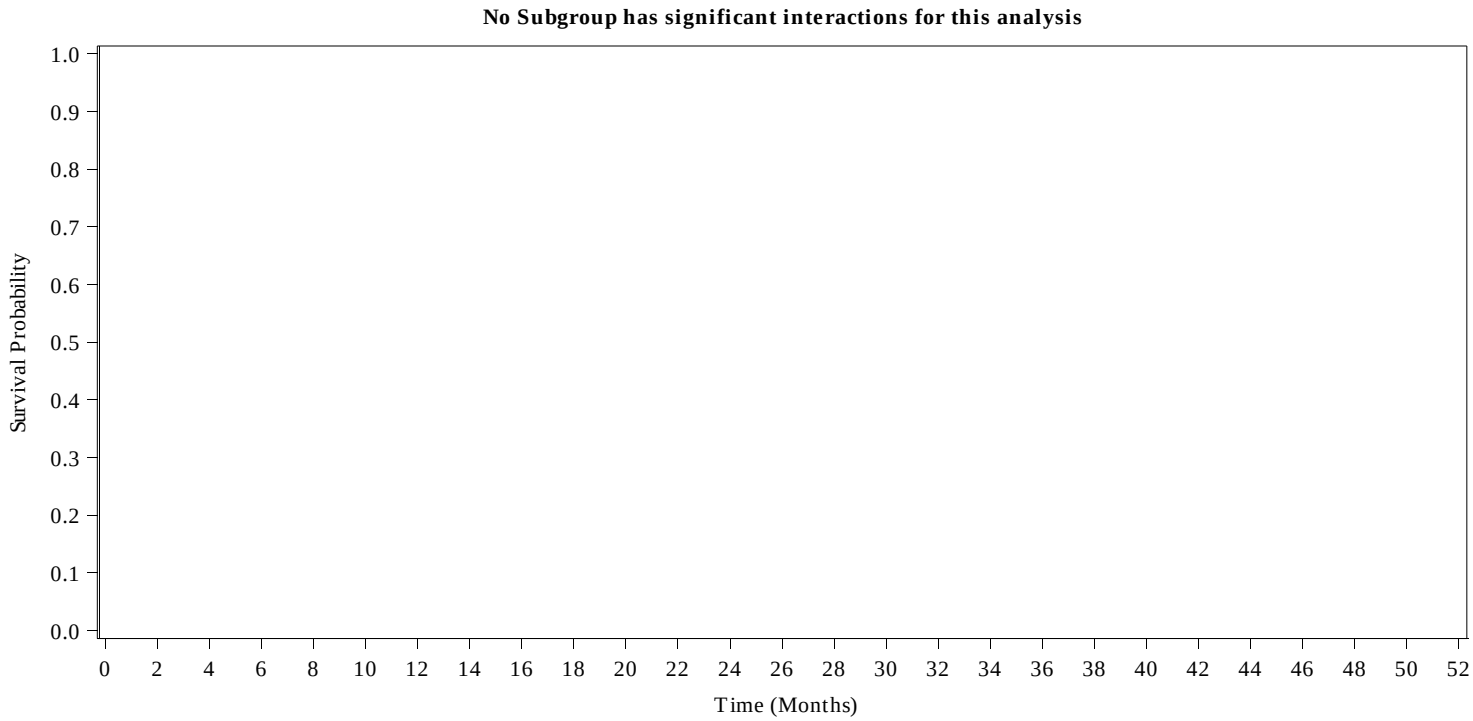
Figure 14.2.1.1.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression-Free Survival		
Events, n (%)	9 (69.2)	15 (88.2)
Progressive Disease	8 (61.5)	14 (82.4)
Death	1 (7.7)	1 (5.9)
Censored, n (%)	4 (30.8)	2 (11.8)
New Anti-Cancer Therapy	1 (7.7)	1 (5.9)
No PD/Death [a]	3 (23.1)	1 (5.9)
Ongoing Without Events	3 (23.1)	1 (5.9)
Two-sided Stratified Log-rank Test p-value [b]	0.2759	
Stratified Hazard Ratio (95% CI) [c]	0.580 (0.216, 1.557)	
Unstratified Hazard Ratio (95% CI) [d]	0.550 (0.238, 1.273)	

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression Free Survival (months)		
Median (95% CI)	6.9 (2.8, NE)	4.4 (1.3, 8.5)
Q1 (95% CI)	5.6 (1.8, 5.7)	2.1 (1.2, 4.1)
Q3 (95% CI)	NR (5.7, NE)	8.5 (4.4, NE)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	76.9 (44.2, 91.9)	58.8 (32.5, 77.8)
6 Months (95% CI)	51.3 (21.9, 74.6)	35.3 (14.5, 57.0)
9 Months (95% CI)	34.2 (10.7, 59.8)	23.5 (7.3, 44.9)
12 Months (95% CI)	34.2 (10.7, 59.8)	17.6 (4.3, 38.3)

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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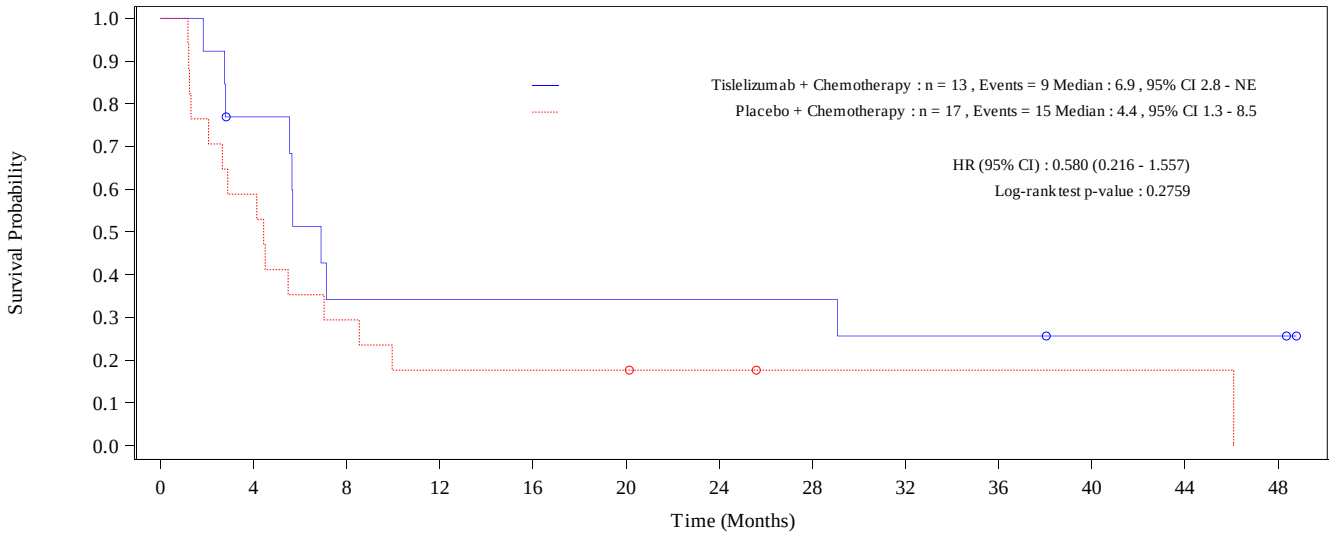
Figure 14.2.4.1:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
Tislelizumab +Chemotherapy	13	13	12	9	9	9	6	5	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	0	
Placebo +Chemotherapy	17	17	13	10	10	7	6	6	5	4	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE, not estimable.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	6 (66.7)	5.7 (2.8, NE)	8	6 (75.0)	3.5 (1.2, NE)	0.525 (0.159, 1.730)	0.2813
Age >= 65	4	3 (75.0)	6.9 (1.8, NE)	9	9 (100.0)	4.5 (1.2, 10.0)	1.095 (0.272, 4.409)	0.8987
Interaction								0.5117
Sex								
Male	9	7 (77.8)	5.7 (1.8, 7.1)	11	10 (90.9)	4.1 (1.2, 10.0)	1.032 (0.376, 2.836)	0.9514
Female	4	2 (50.0)	NR (2.8, NE)	6	5 (83.3)	4.5 (1.2, NE)	0.213 (0.025, 1.842)	0.1226
Interaction								0.1549

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	5.7 (2.8, NE)	10	9 (90.0)	4.5 (1.3, 7.0)	0.988 (0.338, 2.886)	0.9824
1	6	3 (50.0)	NR (1.8, NE)	7	6 (85.7)	2.9 (1.2, NE)	0.330 (0.080, 1.358)	0.1081
Interaction								0.1898

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	5.7 (2.8, NE)	7	6 (85.7)	4.5 (1.2, NE)	0.436 (0.087, 2.183)	0.2995
No	9	7 (77.8)	6.9 (1.8, NE)	10	9 (90.0)	4.3 (1.2, 8.5)	0.562 (0.199, 1.585)	0.2695
Interaction								0.8229

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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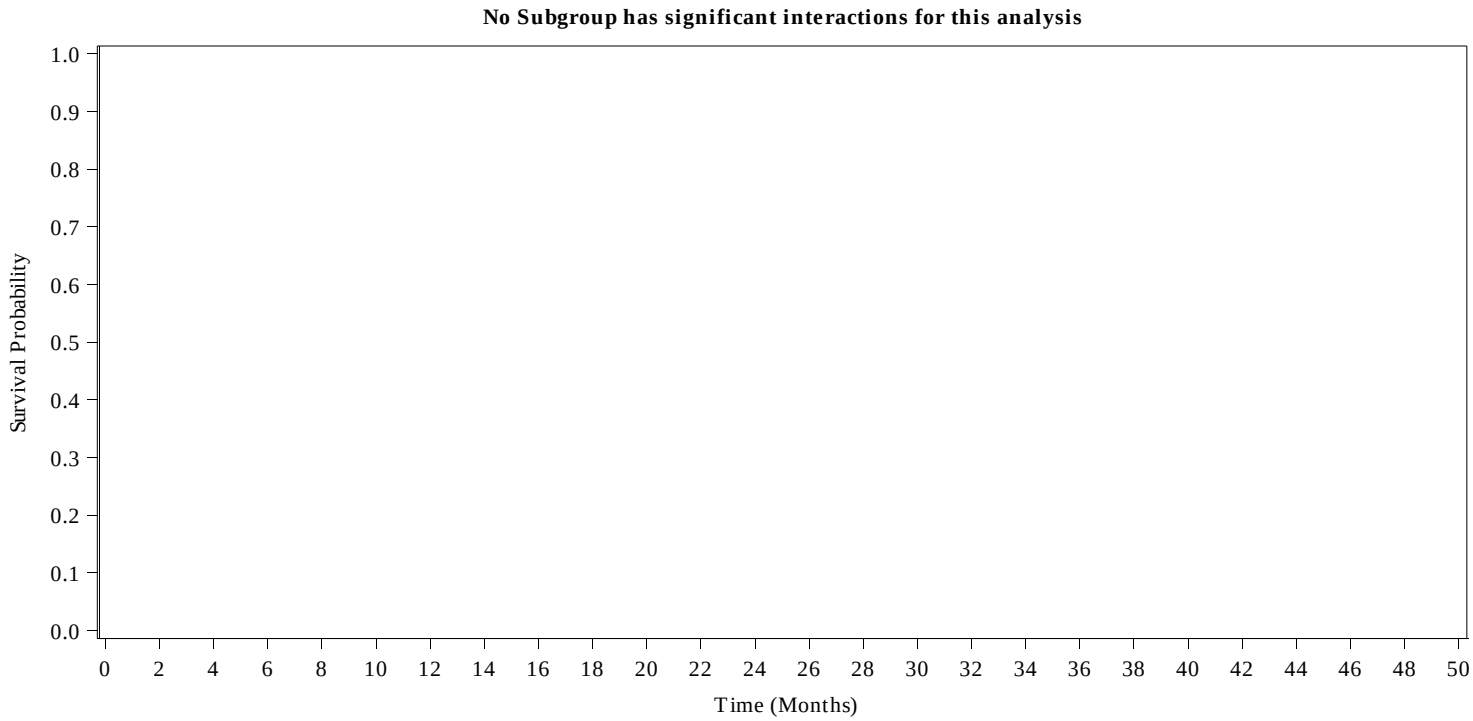
Figure 14.2.4.1.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.2.4.1:
Objective Response
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	11	8				
%	84.6	47.1	5.133 (0.675, 39.019)	1.477 (0.952, 2.292)	27.000 (-5.071, 59.071)	0.1117
Best Overall Response (BOR), n (%)						
Complete Response (CR)	2 (15.4)	1 (5.9)				
Partial Response (PR)	9 (69.2)	7 (41.2)				
Stable Disease (SD) [e]	2 (15.4)	5 (29.4)				
Progressive Disease (PD)	0 (0.0)	4 (23.5)				
Not Evaluable (NE) [c]	0 (0.0)	0 (0.0)				
Not Assessable [d]	0 (0.0)	0 (0.0)				
Disease Control Rate (DCR), n	13	13				
%	100.0	76.5	NE (NE, NE)	1.292 (0.981, 1.702)	22.600 (0.459, 44.741)	0.0975

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE, not estimable.

Percentages were based on N. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[c] Not evaluable is based on RECIST v1.1.

[d] Patients with no post-baseline tumor assessment by the data cutoff, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.

[e] SD includes SD and non-CR/non-PD.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Age								
Age < 65	9	7 (77.8)	8	3 (37.5)	5.833 (0.696, 48.873)	2.074 (0.794, 5.419)	40.278 (-2.887, 83.442)	0.1023
Age >= 65	4	4 (100.0)	9	5 (55.6)	NE (NE, NE)	1.800 (1.003, 3.229)	44.444 (11.981, 76.908)	0.1237
Interaction								0.4682
Sex								
Male	9	8 (88.9)	11	5 (45.5)	9.600 (0.876, 105.166)	1.956 (0.983, 3.888)	43.434 (7.554, 79.315)	0.0483
Female	4	3 (75.0)	6	3 (50.0)	3.000 (0.188, 47.963)	1.500 (0.563, 3.997)	25.000 (-33.321, 83.321)	0.4533
Interaction								0.5300

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
ECOG Performance Score								
0	7	5 (71.4)	10	5 (50.0)	2.500 (0.320, 19.529)	1.429 (0.657, 3.107)	21.429 (-24.182, 67.039)	0.3914
1	6	6 (100.0)	7	3 (42.9)	NE (NE, NE)	2.333 (0.992, 5.489)	57.143 (20.483, 93.803)	0.0325
Interaction								0.1711
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	7	2 (28.6)	7.500 (0.458, 122.696)	2.625 (0.715, 9.640)	46.429 (-7.614, 100.000)	0.1561
No	9	8 (88.9)	10	6 (60.0)	5.333 (0.468, 60.797)	1.481 (0.849, 2.584)	28.889 (-7.765, 65.543)	0.1646
Interaction								0.8566

Source: ADSL, ADTTE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-3y.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-3y.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	66.7	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
Cycle 46		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 48		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 50		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 52		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 56		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 58		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 60		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 64		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
End of Treatment		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	10	16
Completion rate (%) [a]	76.9	94.1
Adjusted completion rate (%) [b]	90.9	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	11
Completion rate (%) [a]	84.6	64.7
Adjusted completion rate (%) [b]	100.0	91.7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	66.7	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-3y.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-3y.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
Cycle 46		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 48		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 50		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 52		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 56		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 58		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 64		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
End of Treatment		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	10	16
Completion rate (%) [a]	76.9	94.1
Adjusted completion rate (%) [b]	90.9	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	8	9
Completion rate (%) [a]	61.5	52.9
Adjusted completion rate (%) [b]	88.9	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-3y.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-3y.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	66.7	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	50.0	100.0
Cycle 46		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 48		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 50		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 52		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 54		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 56		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 58		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 60		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 62		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 64		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
End of Treatment		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	10	16
Completion rate (%) [a]	76.9	94.1
Adjusted completion rate (%) [b]	90.9	100.0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-comp.sas 21OCT2024 08:37 t-14-2-6-1-1-qs-comp-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	63.2 (29.83)		57.8 (25.08)	
	Median	83.3		50.0	
	Q1, Q3	37.5, 83.3		50.0, 75.0	
	Min, Max	0, 83		8, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	74.2 (16.87)	10.8 (26.95)	62.2 (20.14)	5.6 (20.33)
	Median	83.3	4.2	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 8.3	50.0, 83.3	-8.3, 25.0
	Min, Max	33, 92	-17, 67	25, 83	-42, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	75.8 (12.08)	12.5 (28.40)	62.5 (26.94)	5.6 (20.21)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 33.3	58.3, 75.0	0.0, 16.7
	Min, Max	58, 92	-25, 67	8, 100	-33, 50

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	77.8 (13.82)	16.7 (23.57)	60.4 (27.55)	3.5 (26.93)
	Median	83.3	8.3	75.0	4.2
	Q1, Q3	66.7, 83.3	0.0, 41.7	41.7, 79.2	-16.7, 20.8
	Min, Max	50, 92	-8, 50	8, 83	-42, 42
Cycle 5	n	8	8	11	11
	Mean (SD)	78.1 (17.78)	12.5 (19.42)	64.4 (26.38)	3.0 (28.69)
	Median	83.3	4.2	66.7	16.7
	Q1, Q3	70.8, 87.5	0.0, 29.2	41.7, 83.3	-25.0, 16.7
	Min, Max	42, 100	-8, 42	17, 100	-42, 42
Cycle 6	n	7	7	9	9
	Mean (SD)	81.0 (11.50)	6.0 (15.75)	71.3 (24.69)	7.4 (28.09)
	Median	83.3	0.0	83.3	0.0
	Q1, Q3	66.7, 83.3	0.0, 16.7	66.7, 83.3	-8.3, 33.3
	Min, Max	67, 100	-17, 33	17, 100	-33, 50

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	81.0 (15.00)	17.9 (22.79)	85.7 (11.50)	17.9 (26.97)
	Median	83.3	8.3	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 100.0	0.0, 41.7
	Min, Max	50, 100	0, 50	67, 100	-8, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (27.22)	16.7 (23.57)	75.0 (29.34)	6.9 (36.29)
	Median	66.7	25.0	83.3	4.2
	Q1, Q3	50.0, 83.3	0.0, 33.3	83.3, 83.3	-8.3, 41.7
	Min, Max	33, 100	-17, 33	17, 100	-50, 50
Cycle 12	n	3	3	5	5
	Mean (SD)	75.0 (14.43)	36.1 (42.76)	70.0 (21.73)	8.3 (31.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	58.3, 83.3	0.0, 83.3	66.7, 83.3	-8.3, 25.0
	Min, Max	58, 83	0, 83	33, 83	-33, 50

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	80.6 (12.73)	41.7 (30.05)	75.0 (8.33)	16.7 (22.05)
	Median	83.3	50.0	75.0	8.3
	Q1, Q3	66.7, 91.7	8.3, 66.7	66.7, 83.3	0.0, 41.7
	Min, Max	67, 92	8, 67	67, 83	0, 42
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	38.9 (25.46)	66.7 (23.57)	-12.5 (5.89)
	Median	66.7	33.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	16.7, 66.7	50.0, 83.3	-16.7, -8.3
	Min, Max	67, 100	17, 67	50, 83	-17, -8
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (34.69)	16.7 (16.67)	72.2 (19.25)	-5.6 (12.73)
	Median	66.7	16.7	83.3	-8.3
	Q1, Q3	16.7, 83.3	0.0, 33.3	50.0, 83.3	-16.7, 8.3
	Min, Max	17, 83	0, 33	50, 83	-17, 8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	72.2 (19.25)	33.3 (28.87)	80.6 (4.81)	2.8 (9.62)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 83.3	0.0, 50.0	75.0, 83.3	-8.3, 8.3
	Min, Max	50, 83	0, 50	75, 83	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (25.46)	38.9 (19.25)	77.8 (9.62)	0.0 (22.05)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 100.0	16.7, 50.0	66.7, 83.3	-25.0, 16.7
	Min, Max	50, 100	17, 50	67, 83	-25, 17
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	83.3 (0.00)	5.6 (12.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 83.3	-8.3, 16.7
	Min, Max	83, 83	0, 50	83, 83	-8, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	77.8 (9.62)	0.0 (8.33)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	83.3, 83.3	0.0, 50.0	66.7, 83.3	-8.3, 8.3
	Min, Max	83, 83	0, 50	67, 83	-8, 8
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	25.0 (11.79)	83.3 (0.00)	4.2 (17.68)
	Median	83.3	25.0	83.3	4.2
	Q1, Q3	66.7, 100.0	16.7, 33.3	83.3, 83.3	-8.3, 16.7
	Min, Max	67, 100	17, 33	83, 83	-8, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	66.7 (23.57)	50.0 (0.00)	83.3 (0.00)	4.2 (17.68)
	Median	66.7	50.0	83.3	4.2
	Q1, Q3	50.0, 83.3	50.0, 50.0	83.3, 83.3	-8.3, 16.7
	Min, Max	50, 83	50, 50	83, 83	-8, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	61.1 (25.46)	22.2 (19.25)	83.3 (NE)	-8.3 (NE)
	Median	66.7	33.3	83.3	-8.3
	Q1, Q3	33.3, 83.3	0.0, 33.3	83.3, 83.3	-8.3, -8.3
	Min, Max	33, 83	0, 33	83, 83	-8, -8
Cycle 34	n	3	3	1	1
	Mean (SD)	66.7 (33.33)	27.8 (9.62)	75.0 (NE)	-16.7 (NE)
	Median	66.7	33.3	75.0	-16.7
	Q1, Q3	33.3, 100.0	16.7, 33.3	75.0, 75.0	-16.7, -16.7
	Min, Max	33, 100	17, 33	75, 75	-17, -17
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	16.7 (NE)	83.3 (NE)	-8.3 (NE)
	Median	100.0	16.7	83.3	-8.3
	Q1, Q3	100.0, 100.0	16.7, 16.7	83.3, 83.3	-8.3, -8.3
	Min, Max	100, 100	17, 17	83, 83	-8, -8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			91.7 (NE)	0.0 (NE)
	Median			91.7	0.0
	Q1, Q3			91.7, 91.7	0.0, 0.0
	Min, Max			92, 92	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	1	1	1	1
	Mean (SD)	50.0 (NE)	50.0 (NE)	75.0 (NE)	-16.7 (NE)
	Median	50.0	50.0	75.0	-16.7
	Q1, Q3	50.0, 50.0	50.0, 50.0	75.0, 75.0	-16.7, -16.7
	Min, Max	50, 50	50, 50	75, 75	-17, -17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 46	n	1	1	1	1
	Mean (SD)	50.0 (NE)	50.0 (NE)	83.3 (NE)	-8.3 (NE)
	Median	50.0	50.0	83.3	-8.3
	Q1, Q3	50.0, 50.0	50.0, 50.0	83.3, 83.3	-8.3, -8.3
	Min, Max	50, 50	50, 50	83, 83	-8, -8
Cycle 48	n	1	1	0	0
	Mean (SD)	50.0 (NE)	50.0 (NE)		
	Median	50.0	50.0		
	Q1, Q3	50.0, 50.0	50.0, 50.0		
	Min, Max	50, 50	50, 50		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 52	n	1	1	0	0
	Mean (SD)	50.0 (NE)	50.0 (NE)		
	Median	50.0	50.0		
	Q1, Q3	50.0, 50.0	50.0, 50.0		
	Min, Max	50, 50	50, 50		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		
Cycle 64	n	1	1	0	0
	Mean (SD)	25.0 (NE)	25.0 (NE)		
	Median	25.0	25.0		
	Q1, Q3	25.0, 25.0	25.0, 25.0		
	Min, Max	25, 25	25, 25		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	72.2 (9.32)	1.9 (26.93)	59.4 (25.98)	1.0 (22.33)
	Median	66.7	-8.3	66.7	0.0
	Q1, Q3	66.7, 83.3	-16.7, 0.0	41.7, 75.0	-8.3, 8.3
	Min, Max	58, 83	-25, 58	0, 100	-50, 42
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	56.9 (22.14)	-6.3 (13.35)	44.1 (23.89)	-13.7 (21.84)
	Median	66.7	-8.3	50.0	-8.3
	Q1, Q3	45.8, 66.7	-16.7, 0.0	33.3, 66.7	-25.0, 0.0
	Min, Max	17, 83	-25, 17	0, 75	-50, 25

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.7 (21.84)		87.1 (14.23)	
	Median	100.0		86.7	
	Q1, Q3	70.0, 100.0		86.7, 93.3	
	Min, Max	47, 100		47, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	87.3 (18.18)	2.0 (11.78)	77.3 (22.65)	-8.9 (13.25)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 93.3	-13.3, 0.0
	Min, Max	53, 100	-20, 27	20, 100	-40, 13
Cycle 3	n	10	10	12	12
	Mean (SD)	88.0 (19.58)	2.7 (10.04)	73.9 (21.36)	-14.4 (11.66)
	Median	100.0	0.0	80.0	-10.0
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 86.7	-26.7, -6.7
	Min, Max	47, 100	-7, 27	20, 100	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.9 (23.67)	2.2 (14.53)	75.6 (23.33)	-12.8 (12.86)
	Median	100.0	0.0	80.0	-13.3
	Q1, Q3	86.7, 100.0	0.0, 0.0	66.7, 93.3	-23.3, 0.0
	Min, Max	33, 100	-20, 33	13, 100	-33, 7
Cycle 5	n	8	8	11	11
	Mean (SD)	86.7 (24.43)	-0.8 (10.95)	82.4 (15.57)	-9.7 (13.78)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	-3.3, 0.0	66.7, 100.0	-26.7, 0.0
	Min, Max	33, 100	-20, 20	60, 100	-27, 13
Cycle 6	n	7	7	9	9
	Mean (SD)	94.3 (15.12)	1.9 (5.04)	83.7 (12.96)	-8.9 (11.55)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	100.0, 100.0	0.0, 0.0	80.0, 93.3	-13.3, 0.0
	Min, Max	60, 100	0, 13	60, 100	-27, 7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	82.9 (27.72)	-2.9 (8.48)	89.5 (12.68)	-4.8 (10.69)
	Median	100.0	0.0	93.3	0.0
	Q1, Q3	53.3, 100.0	-6.7, 0.0	80.0, 100.0	-6.7, 0.0
	Min, Max	33, 100	-20, 7	67, 100	-27, 7
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (35.69)	-8.3 (8.39)	86.7 (26.67)	-6.7 (26.67)
	Median	70.0	-6.7	100.0	0.0
	Q1, Q3	36.7, 96.7	-13.3, -3.3	86.7, 100.0	0.0, 6.7
	Min, Max	27, 100	-20, 0	33, 100	-60, 13
Cycle 12	n	3	3	5	5
	Mean (SD)	64.4 (30.79)	-2.2 (3.85)	85.3 (15.20)	-6.7 (13.33)
	Median	46.7	0.0	86.7	0.0
	Q1, Q3	46.7, 100.0	-6.7, 0.0	73.3, 100.0	-13.3, 0.0
	Min, Max	47, 100	-7, 0	67, 100	-27, 7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	91.1 (7.70)	24.4 (21.43)	88.9 (13.88)	-4.4 (13.88)
	Median	86.7	33.3	93.3	0.0
	Q1, Q3	86.7, 100.0	0.0, 40.0	73.3, 100.0	-20.0, 6.7
	Min, Max	87, 100	0, 40	73, 100	-20, 7
Cycle 16	n	3	3	2	2
	Mean (SD)	75.6 (23.41)	8.9 (15.40)	83.3 (23.57)	-10.0 (23.57)
	Median	73.3	0.0	83.3	-10.0
	Q1, Q3	53.3, 100.0	0.0, 26.7	66.7, 100.0	-26.7, 6.7
	Min, Max	53, 100	0, 27	67, 100	-27, 7
Cycle 18	n	3	3	3	3
	Mean (SD)	73.3 (24.04)	6.7 (11.55)	75.6 (10.18)	-15.6 (13.88)
	Median	66.7	0.0	73.3	-20.0
	Q1, Q3	53.3, 100.0	0.0, 20.0	66.7, 86.7	-26.7, 0.0
	Min, Max	53, 100	0, 20	67, 87	-27, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	77.8 (23.41)	11.1 (19.25)	82.2 (13.88)	-8.9 (15.40)
	Median	80.0	0.0	86.7	0.0
	Q1, Q3	53.3, 100.0	0.0, 33.3	66.7, 93.3	-26.7, 0.0
	Min, Max	53, 100	0, 33	67, 93	-27, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	73.3 (30.55)	6.7 (24.04)	93.3 (6.67)	2.2 (3.85)
	Median	80.0	0.0	93.3	0.0
	Q1, Q3	40.0, 100.0	-13.3, 33.3	86.7, 100.0	0.0, 6.7
	Min, Max	40, 100	-13, 33	87, 100	0, 7
Cycle 24	n	2	2	3	3
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	82.2 (10.18)	-8.9 (13.88)
	Median	90.0	16.7	80.0	-13.3
	Q1, Q3	80.0, 100.0	0.0, 33.3	73.3, 93.3	-20.0, 6.7
	Min, Max	80, 100	0, 33	73, 93	-20, 7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	86.7 (18.86)	13.3 (18.86)	86.7 (6.67)	-4.4 (10.18)
	Median	86.7	13.3	86.7	-6.7
	Q1, Q3	73.3, 100.0	0.0, 26.7	80.0, 93.3	-13.3, 6.7
	Min, Max	73, 100	0, 27	80, 93	-13, 7
Cycle 28	n	2	2	2	2
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	90.0 (14.14)	-3.3 (14.14)
	Median	90.0	16.7	90.0	-3.3
	Q1, Q3	80.0, 100.0	0.0, 33.3	80.0, 100.0	-13.3, 6.7
	Min, Max	80, 100	0, 33	80, 100	-13, 7
Cycle 30	n	2	2	2	2
	Mean (SD)	76.7 (14.14)	26.7 (18.86)	83.3 (23.57)	-10.0 (23.57)
	Median	76.7	26.7	83.3	-10.0
	Q1, Q3	66.7, 86.7	13.3, 40.0	66.7, 100.0	-26.7, 6.7
	Min, Max	67, 87	13, 40	67, 100	-27, 7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	80.0 (24.04)	13.3 (23.09)	93.3 (NE)	0.0 (NE)
	Median	86.7	0.0	93.3	0.0
	Q1, Q3	53.3, 100.0	0.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	53, 100	0, 40	93, 93	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	73.3 (35.28)	6.7 (30.55)	93.3 (NE)	0.0 (NE)
	Median	86.7	0.0	93.3	0.0
	Q1, Q3	33.3, 100.0	-20.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	33, 100	-20, 40	93, 93	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	100.0 (NE)	6.7 (NE)
	Median	100.0	0.0	100.0	6.7
	Q1, Q3	100.0, 100.0	0.0, 0.0	100.0, 100.0	6.7, 6.7
	Min, Max	100, 100	0, 0	100, 100	7, 7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	60.0 (NE)	6.7 (NE)	86.7 (NE)	-6.7 (NE)
	Median	60.0	6.7	86.7	-6.7
	Q1, Q3	60.0, 60.0	6.7, 6.7	86.7, 86.7	-6.7, -6.7
	Min, Max	60, 60	7, 7	87, 87	-7, -7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	13.3 (NE)	93.3 (NE)	0.0 (NE)
	Median	66.7	13.3	93.3	0.0
	Q1, Q3	66.7, 66.7	13.3, 13.3	93.3, 93.3	0.0, 0.0
	Min, Max	67, 67	13, 13	93, 93	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	53.3 (NE)	0.0 (NE)		
	Median	53.3	0.0		
	Q1, Q3	53.3, 53.3	0.0, 0.0		
	Min, Max	53, 53	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	60.0 (NE)	6.7 (NE)		
	Median	60.0	6.7		
	Q1, Q3	60.0, 60.0	6.7, 6.7		
	Min, Max	60, 60	7, 7		
Cycle 52	n	1	1	0	0
	Mean (SD)	40.0 (NE)	-13.3 (NE)		
	Median	40.0	-13.3		
	Q1, Q3	40.0, 40.0	-13.3, -13.3		
	Min, Max	40, 40	-13, -13		
Cycle 56	n	1	1	0	0
	Mean (SD)	60.0 (NE)	6.7 (NE)		
	Median	60.0	6.7		
	Q1, Q3	60.0, 60.0	6.7, 6.7		
	Min, Max	60, 60	7, 7		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	46.7 (NE)	-6.7 (NE)		
	Median	46.7	-6.7		
	Q1, Q3	46.7, 46.7	-6.7, -6.7		
	Min, Max	47, 47	-7, -7		
Cycle 60	n	1	1	0	0
	Mean (SD)	46.7 (NE)	-6.7 (NE)		
	Median	46.7	-6.7		
	Q1, Q3	46.7, 46.7	-6.7, -6.7		
	Min, Max	47, 47	-7, -7		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-20.0 (NE)		
	Median	33.3	-20.0		
	Q1, Q3	33.3, 33.3	-20.0, -20.0		
	Min, Max	33, 33	-20, -20		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	89.6 (9.49)	0.7 (20.40)	72.1 (25.67)	-15.0 (16.95)
	Median	86.7	0.0	83.3	-6.7
	Q1, Q3	86.7, 100.0	-13.3, 0.0	60.0, 86.7	-26.7, 0.0
	Min, Max	73, 100	-27, 33	7, 100	-53, 0
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	76.7 (25.66)	-10.0 (9.64)	60.4 (23.39)	-26.7 (15.63)
	Median	83.3	-6.7	66.7	-26.7
	Q1, Q3	63.3, 96.7	-20.0, 0.0	46.7, 80.0	-33.3, -13.3
	Min, Max	27, 100	-27, 0	7, 87	-60, -7

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.1 (21.12)		79.4 (26.70)	
	Median	100.0		100.0	
	Q1, Q3	75.0, 100.0		66.7, 100.0	
	Min, Max	33, 100		17, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	88.3 (17.66)	3.3 (7.03)	71.1 (31.16)	-8.9 (18.76)
	Median	100.0	0.0	83.3	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 17	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	88.3 (22.29)	3.3 (10.54)	70.8 (29.41)	-9.7 (18.06)
	Median	100.0	0.0	75.0	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 91.7	-16.7, 0.0
	Min, Max	33, 100	0, 33	0, 100	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	83.3 (33.33)	-1.9 (26.93)	70.8 (32.66)	-9.7 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	85.4 (27.37)	-2.1 (5.89)	78.8 (21.20)	-7.6 (18.80)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	90.5 (25.20)	0.0 (0.00)	79.6 (18.22)	-7.4 (16.90)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	0, 0	50, 100	-33, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	83.3 (28.87)	-2.4 (6.30)	95.2 (12.60)	0.0 (19.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	50.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-17, 0	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	58.3 (50.00)	-16.7 (19.25)	88.9 (27.22)	-5.6 (32.77)
	Median	66.7	-16.7	100.0	0.0
	Q1, Q3	16.7, 100.0	-33.3, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	55.6 (50.92)	-11.1 (19.25)	73.3 (30.28)	-20.0 (21.73)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	0.0, 100.0	-33.3, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-50, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	16.7 (16.67)	83.3 (28.87)	-16.7 (28.87)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	50.0, 100.0	-50.0, 0.0
	Min, Max	67, 100	0, 33	50, 100	-50, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	66.7 (33.33)	0.0 (0.00)	83.3 (23.57)	-16.7 (23.57)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	33.3, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	0, 0	67, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (38.49)	-11.1 (19.25)	88.9 (19.25)	-11.1 (19.25)
	Median	33.3	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	55.6 (50.92)	-11.1 (50.92)	88.9 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-67, 33	67, 100	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	72.2 (25.46)	5.6 (25.46)	83.3 (16.67)	-16.7 (16.67)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	50.0, 100.0	-16.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	50, 100	-17, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	83.3 (16.67)	-16.7 (16.67)
	Median	83.3	16.7	83.3	-16.7
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	88.9 (19.25)	-11.1 (19.25)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	83.3 (23.57)	-16.7 (23.57)
	Median	83.3	16.7	83.3	-16.7
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	66.7 (0.00)	16.7 (23.57)	83.3 (23.57)	-16.7 (23.57)
	Median	66.7	16.7	83.3	-16.7
	Q1, Q3	66.7, 66.7	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 67	0, 33	67, 100	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	55.6 (50.92)	-11.1 (50.92)	100.0 (NE)	0.0 (NE)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	0, 100	-67, 33	100, 100	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	66.7 (33.33)	0.0 (33.33)	100.0 (NE)	0.0 (NE)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-33, 33	100, 100	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	100.0 (NE)	0.0 (NE)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	100, 100	0, 0	100, 100	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-16.7 (NE)
	Median			83.3	-16.7
	Q1, Q3			83.3, 83.3	-16.7, -16.7
	Min, Max			83, 83	-17, -17
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-33.3 (NE)	66.7 (NE)	-33.3 (NE)
	Median	33.3	-33.3	66.7	-33.3
	Q1, Q3	33.3, 33.3	-33.3, -33.3	66.7, 66.7	-33.3, -33.3
	Min, Max	33, 33	-33, -33	67, 67	-33, -33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-33.3 (NE)	66.7 (NE)	-33.3 (NE)
	Median	33.3	-33.3	66.7	-33.3
	Q1, Q3	33.3, 33.3	-33.3, -33.3	66.7, 66.7	-33.3, -33.3
	Min, Max	33, 33	-33, -33	67, 67	-33, -33
Cycle 48	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-16.7 (NE)		
	Median	50.0	-16.7		
	Q1, Q3	50.0, 50.0	-16.7, -16.7		
	Min, Max	50, 50	-17, -17		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-16.7 (NE)		
	Median	50.0	-16.7		
	Q1, Q3	50.0, 50.0	-16.7, -16.7		
	Min, Max	50, 50	-17, -17		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 56	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-16.7 (NE)		
	Median	50.0	-16.7		
	Q1, Q3	50.0, 50.0	-16.7, -16.7		
	Min, Max	50, 50	-17, -17		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-50.0 (NE)		
	Median	16.7	-50.0		
	Q1, Q3	16.7, 16.7	-50.0, -50.0		
	Min, Max	17, 17	-50, -50		
Cycle 60	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-50.0 (NE)		
	Median	16.7	-50.0		
	Q1, Q3	16.7, 16.7	-50.0, -50.0		
	Min, Max	17, 17	-50, -50		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	87.0 (16.20)	0.0 (22.05)	69.8 (29.32)	-10.4 (15.96)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	58.3, 100.0	-16.7, 0.0
	Min, Max	67, 100	-33, 33	0, 100	-50, 0
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	69.4 (36.81)	-16.7 (20.10)	53.9 (29.77)	-25.5 (18.74)
	Median	75.0	-16.7	66.7	-33.3
	Q1, Q3	58.3, 100.0	-25.0, 0.0	33.3, 66.7	-33.3, -16.7
	Min, Max	0, 100	-67, 0	0, 100	-67, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	72.9 (27.55)		75.5 (20.08)	
	Median	83.3		75.0	
	Q1, Q3	62.5, 87.5		66.7, 91.7	
	Min, Max	8, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	90.8 (9.98)	15.8 (19.42)	73.9 (19.89)	-1.1 (22.90)
	Median	91.7	8.3	75.0	0.0
	Q1, Q3	83.3, 100.0	8.3, 16.7	66.7, 83.3	-16.7, 0.0
	Min, Max	75, 100	0, 67	17, 100	-25, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	94.2 (11.15)	19.2 (23.59)	75.0 (12.31)	0.7 (17.21)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	91.7, 100.0	8.3, 16.7	66.7, 83.3	-8.3, 8.3
	Min, Max	67, 100	0, 83	50, 100	-25, 42

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	87.0 (20.46)	13.0 (17.73)	75.0 (22.47)	0.7 (16.84)
	Median	100.0	16.7	79.2	0.0
	Q1, Q3	83.3, 100.0	0.0, 16.7	62.5, 91.7	-8.3, 8.3
	Min, Max	42, 100	-17, 42	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	89.6 (15.27)	14.6 (15.91)	75.8 (19.17)	0.8 (22.19)
	Median	95.8	12.5	83.3	0.0
	Q1, Q3	83.3, 100.0	4.2, 16.7	66.7, 83.3	-8.3, 16.7
	Min, Max	58, 100	0, 50	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	10.7 (7.93)	77.8 (18.63)	-2.8 (18.16)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 16.7	66.7, 91.7	-16.7, 8.3
	Min, Max	67, 100	0, 17	42, 100	-25, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	89.3 (14.20)	15.5 (20.65)	86.9 (10.60)	3.6 (10.60)
	Median	100.0	16.7	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 16.7	83.3, 91.7	0.0, 8.3
	Min, Max	67, 100	0, 58	67, 100	-8, 25
Cycle 10	n	4	4	6	6
	Mean (SD)	79.2 (14.43)	16.7 (28.87)	86.1 (26.70)	2.8 (21.52)
	Median	79.2	8.3	100.0	4.2
	Q1, Q3	66.7, 91.7	0.0, 33.3	83.3, 100.0	0.0, 8.3
	Min, Max	67, 92	-8, 58	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	94.4 (9.62)	38.9 (47.39)	81.7 (27.89)	1.7 (23.86)
	Median	100.0	25.0	91.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 91.7	83.3, 100.0	0.0, 8.3
	Min, Max	83, 100	0, 92	33, 100	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	86.1 (12.73)	30.6 (33.68)	80.6 (12.73)	0.0 (16.67)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 66.7	66.7, 91.7	-16.7, 16.7
	Min, Max	75, 100	0, 67	67, 92	-17, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (35.36)	-12.5 (17.68)
	Median	66.7	8.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	0.0, 58.3	41.7, 91.7	-25.0, 0.0
	Min, Max	67, 100	0, 58	42, 92	-25, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	80.6 (17.35)	25.0 (30.05)	83.3 (16.67)	-2.8 (4.81)
	Median	75.0	16.7	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 58.3	66.7, 100.0	-8.3, 0.0
	Min, Max	67, 100	0, 58	67, 100	-8, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	38.9 (37.58)	86.1 (24.06)	0.0 (8.33)
	Median	100.0	41.7	100.0	0.0
	Q1, Q3	83.3, 100.0	0.0, 75.0	58.3, 100.0	-8.3, 8.3
	Min, Max	83, 100	0, 75	58, 100	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (8.33)	-19.4 (24.06)
	Median	66.7	8.3	66.7	-33.3
	Q1, Q3	66.7, 100.0	0.0, 58.3	58.3, 75.0	-33.3, 8.3
	Min, Max	67, 100	0, 58	58, 75	-33, 8
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	4.2 (5.89)	75.0 (0.00)	-11.1 (17.35)
	Median	83.3	4.2	75.0	-16.7
	Q1, Q3	66.7, 100.0	0.0, 8.3	75.0, 75.0	-25.0, 8.3
	Min, Max	67, 100	0, 8	75, 75	-25, 8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	91.7 (11.79)	12.5 (17.68)	80.6 (12.73)	-5.6 (25.46)
	Median	91.7	12.5	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 25.0	66.7, 91.7	-33.3, 16.7
	Min, Max	83, 100	0, 25	67, 92	-33, 17
Cycle 28	n	2	2	2	2
	Mean (SD)	87.5 (17.68)	8.3 (11.79)	75.0 (11.79)	-4.2 (5.89)
	Median	87.5	8.3	75.0	-4.2
	Q1, Q3	75.0, 100.0	0.0, 16.7	66.7, 83.3	-8.3, 0.0
	Min, Max	75, 100	0, 17	67, 83	-8, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	83.3 (11.79)	50.0 (47.14)	70.8 (17.68)	-8.3 (0.00)
	Median	83.3	50.0	70.8	-8.3
	Q1, Q3	75.0, 91.7	16.7, 83.3	58.3, 83.3	-8.3, -8.3
	Min, Max	75, 92	17, 83	58, 83	-8, -8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	80.6 (17.35)	25.0 (36.32)	83.3 (NE)	-8.3 (NE)
	Median	75.0	8.3	83.3	-8.3
	Q1, Q3	66.7, 100.0	0.0, 66.7	83.3, 83.3	-8.3, -8.3
	Min, Max	67, 100	0, 67	83, 83	-8, -8
Cycle 34	n	3	3	1	1
	Mean (SD)	83.3 (28.87)	27.8 (24.06)	66.7 (NE)	-25.0 (NE)
	Median	100.0	41.7	66.7	-25.0
	Q1, Q3	50.0, 100.0	0.0, 41.7	66.7, 66.7	-25.0, -25.0
	Min, Max	50, 100	0, 42	67, 67	-25, -25
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	83.3 (NE)	-8.3 (NE)
	Median	100.0	0.0	83.3	-8.3
	Q1, Q3	100.0, 100.0	0.0, 0.0	83.3, 83.3	-8.3, -8.3
	Min, Max	100, 100	0, 0	83, 83	-8, -8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	1	1	1	1
	Mean (SD)	75.0 (NE)	66.7 (NE)	83.3 (NE)	-8.3 (NE)
	Median	75.0	66.7	83.3	-8.3
	Q1, Q3	75.0, 75.0	66.7, 66.7	83.3, 83.3	-8.3, -8.3
	Min, Max	75, 75	67, 67	83, 83	-8, -8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 46	n	1	1	1	1
	Mean (SD)	83.3 (NE)	75.0 (NE)	75.0 (NE)	-16.7 (NE)
	Median	83.3	75.0	75.0	-16.7
	Q1, Q3	83.3, 83.3	75.0, 75.0	75.0, 75.0	-16.7, -16.7
	Min, Max	83, 83	75, 75	75, 75	-17, -17
Cycle 48	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	50.0 (NE)	41.7 (NE)		
	Median	50.0	41.7		
	Q1, Q3	50.0, 50.0	41.7, 41.7		
	Min, Max	50, 50	42, 42		
Cycle 60	n	1	1	0	0
	Mean (SD)	58.3 (NE)	50.0 (NE)		
	Median	58.3	50.0		
	Q1, Q3	58.3, 58.3	50.0, 50.0		
	Min, Max	58, 58	50, 50		
Cycle 64	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	88.0 (15.09)	6.5 (24.92)	70.8 (21.73)	-7.3 (17.45)
	Median	91.7	8.3	75.0	-4.2
	Q1, Q3	91.7, 100.0	0.0, 16.7	58.3, 87.5	-25.0, 8.3
	Min, Max	58, 100	-42, 42	25, 100	-33, 25
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	70.8 (23.44)	-2.1 (18.84)	58.8 (19.43)	-16.7 (13.82)
	Median	75.0	0.0	66.7	-16.7
	Q1, Q3	62.5, 87.5	-12.5, 8.3	41.7, 75.0	-25.0, -8.3
	Min, Max	17, 100	-42, 33	17, 83	-33, 8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	94.4 (14.79)		78.4 (18.41)	
	Median	100.0		83.3	
	Q1, Q3	100.0, 100.0		66.7, 100.0	
	Min, Max	50, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	93.3 (11.65)	0.0 (17.57)	75.6 (28.78)	-1.1 (17.21)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-33, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	91.7 (21.15)	-1.7 (9.46)	80.6 (17.16)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-8.3, 0.0
	Min, Max	33, 100	-17, 17	50, 100	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	94.4 (11.79)	1.9 (10.02)	80.6 (24.45)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	75.0, 100.0	0.0, 16.7
	Min, Max	67, 100	-17, 17	33, 100	-50, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	87.5 (23.15)	-6.3 (17.68)	83.3 (26.87)	0.0 (27.89)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 16.7
	Min, Max	50, 100	-50, 0	33, 100	-50, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	92.9 (18.90)	0.0 (0.00)	83.3 (16.67)	0.0 (16.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	50, 100	-33, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	90.5 (16.27)	-2.4 (15.00)	90.5 (13.11)	7.1 (16.27)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	67, 100	-33, 17	67, 100	-17, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	87.5 (25.00)	0.0 (0.00)	83.3 (25.82)	0.0 (18.26)
	Median	100.0	0.0	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	33, 100	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	77.8 (38.49)	-5.6 (9.62)	73.3 (27.89)	-6.7 (27.89)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	33.3, 100.0	-16.7, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	77.8 (19.25)	0.0 (0.00)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	66.7 (47.14)	-16.7 (23.57)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 16.7	33.3, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 17	33, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	88.9 (9.62)	5.6 (25.46)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	83.3, 100.0	-16.7, 33.3	66.7, 100.0	0.0, 0.0
	Min, Max	83, 100	-17, 33	67, 100	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	83, 100	0, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	83.3 (23.57)	0.0 (0.00)
	Median	83.3	8.3	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	66.7 (47.14)	-16.7 (23.57)
	Median	83.3	8.3	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 16.7	33.3, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 17	33, 100	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	100.0 (NE)	0.0 (NE)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	100, 100	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	100.0 (NE)	0.0 (NE)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	100, 100	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	100.0 (NE)	0.0 (NE)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	100, 100	0, 0	100, 100	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	83.3 (NE)	-16.7 (NE)
	Median	66.7	-33.3	83.3	-16.7
	Q1, Q3	66.7, 66.7	-33.3, -33.3	83.3, 83.3	-16.7, -16.7
	Min, Max	67, 67	-33, -33	83, 83	-17, -17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	83.3 (NE)	-16.7 (NE)	66.7 (NE)	-33.3 (NE)
	Median	83.3	-16.7	66.7	-33.3
	Q1, Q3	83.3, 83.3	-16.7, -16.7	66.7, 66.7	-33.3, -33.3
	Min, Max	83, 83	-17, -17	67, 67	-33, -33
Cycle 48	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 64	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	98.1 (5.56)	5.6 (11.79)	72.9 (27.13)	-6.3 (19.12)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-25.0, 0.0
	Min, Max	83, 100	0, 33	0, 100	-33, 33
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	83.3 (23.57)	-11.1 (19.25)	61.8 (27.49)	-16.7 (19.54)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	-25.0, 0.0	33.3, 83.3	-33.3, 0.0
	Min, Max	33, 100	-50, 17	0, 100	-50, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	83.3 (21.32)		80.4 (17.91)	
	Median	91.7		83.3	
	Q1, Q3	66.7, 100.0		66.7, 100.0	
	Min, Max	33, 100		50, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	85.0 (18.34)	0.0 (15.71)	68.9 (28.08)	-10.0 (23.40)
	Median	91.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	-17, 33	0, 100	-67, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	90.0 (17.92)	5.0 (11.25)	76.4 (21.86)	-6.9 (19.41)
	Median	100.0	0.0	75.0	-8.3
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 33	33, 100	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.2 (17.57)	0.0 (16.67)	69.4 (25.46)	-13.9 (19.89)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 0.0	50.0, 91.7	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	91.7 (15.43)	0.0 (17.82)	71.2 (24.82)	-15.2 (22.92)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-50, 17
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	4.8 (12.60)	83.3 (16.67)	-5.6 (18.63)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	85.7 (17.82)	-4.8 (23.00)	88.1 (15.85)	-2.4 (20.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	-33, 33	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (43.03)	-41.7 (41.94)	83.3 (27.89)	-5.6 (25.09)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	16.7, 83.3	-66.7, -16.7	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-100, 0	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	83.3 (28.87)	-3.3 (24.72)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	33, 100	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 0	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	58.3 (35.36)	-25.0 (11.79)
	Median	66.7	0.0	58.3	-25.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	33.3, 83.3	-33.3, -16.7
	Min, Max	67, 100	-33, 0	33, 83	-33, -17
Cycle 18	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	66.7 (33.33)	-22.2 (38.49)	83.3 (16.67)	-5.6 (9.62)
	Median	66.7	0.0	83.3	0.0
	Q1, Q3	33.3, 100.0	-66.7, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-67, 0	67, 100	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	77.8 (19.25)	-11.1 (19.25)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 0	67, 100	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	83.3 (16.67)	-5.6 (9.62)
	Median	83.3	0.0	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	67, 100	-17, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	66.7 (0.00)	-16.7 (23.57)
	Median	83.3	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 66.7	-33.3, 0.0
	Min, Max	67, 100	0, 0	67, 67	-33, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	66.7 (0.00)	-16.7 (23.57)	75.0 (11.79)	-8.3 (11.79)
	Median	66.7	-16.7	75.0	-8.3
	Q1, Q3	66.7, 66.7	-33.3, 0.0	66.7, 83.3	-16.7, 0.0
	Min, Max	67, 67	-33, 0	67, 83	-17, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	66.7 (33.33)	-22.2 (38.49)	100.0 (NE)	0.0 (NE)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-67, 0	100, 100	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	55.6 (19.25)	-33.3 (33.33)	100.0 (NE)	0.0 (NE)
	Median	66.7	-33.3	100.0	0.0
	Q1, Q3	33.3, 66.7	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-67, 0	100, 100	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	66.7 (NE)	-33.3 (NE)
	Median	100.0	0.0	66.7	-33.3
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 66.7	-33.3, -33.3
	Min, Max	100, 100	0, 0	67, 67	-33, -33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	66.7 (NE)	-33.3 (NE)
	Median	33.3	-66.7	66.7	-33.3
	Q1, Q3	33.3, 33.3	-66.7, -66.7	66.7, 66.7	-33.3, -33.3
	Min, Max	33, 33	-67, -67	67, 67	-33, -33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	66.7 (NE)	-33.3 (NE)
	Median	66.7	-33.3	66.7	-33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	66.7, 66.7	-33.3, -33.3
	Min, Max	67, 67	-33, -33	67, 67	-33, -33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		
Cycle 52	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 60	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-83.3 (NE)		
	Median	16.7	-83.3		
	Q1, Q3	16.7, 16.7	-83.3, -83.3		
	Min, Max	17, 17	-83, -83		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-100.0 (NE)		
	Median	0.0	-100.0		
	Q1, Q3	0.0, 0.0	-100.0, -100.0		
	Min, Max	0, 0	-100, -100		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	87.0 (20.03)	7.4 (16.90)	67.7 (33.04)	-13.5 (26.68)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	58.3, 100.0	-33.3, 0.0
	Min, Max	50, 100	-17, 33	0, 100	-67, 33
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	65.3 (29.69)	-18.1 (29.69)	50.0 (27.00)	-30.4 (18.85)
	Median	66.7	-16.7	50.0	-33.3
	Q1, Q3	50.0, 91.7	-25.0, 0.0	33.3, 66.7	-50.0, -16.7
	Min, Max	0, 100	-100, 17	0, 100	-67, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	24.1 (31.72)		33.3 (22.57)	
	Median	5.6		33.3	
	Q1, Q3	0.0, 50.0		22.2, 44.4	
	Min, Max	0, 89		0, 78	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.6 (21.72)	-8.9 (23.31)	41.5 (26.05)	9.6 (18.24)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-11.1, 0.0	22.2, 44.4	0.0, 22.2
	Min, Max	0, 56	-67, 22	0, 100	-11, 56
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (25.01)	-4.4 (15.89)	39.8 (23.43)	8.3 (13.50)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 44.4	-11.1, 0.0	27.8, 55.6	0.0, 16.7
	Min, Max	0, 67	-44, 11	11, 89	-11, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	23.5 (30.65)	-1.2 (10.31)	42.6 (28.36)	11.1 (22.72)
	Median	11.1	0.0	44.4	5.6
	Q1, Q3	0.0, 33.3	0.0, 0.0	16.7, 61.1	0.0, 33.3
	Min, Max	0, 89	-22, 11	0, 89	-33, 44
Cycle 5	n	8	8	11	11
	Mean (SD)	15.3 (25.85)	-5.6 (10.29)	32.3 (26.04)	5.1 (20.71)
	Median	0.0	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	-11.1, 0.0	11.1, 44.4	0.0, 22.2
	Min, Max	0, 67	-22, 0	0, 89	-44, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	12.7 (25.20)	1.6 (4.20)	29.6 (21.52)	1.2 (15.16)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 22.2	0.0, 0.0	22.2, 33.3	-11.1, 11.1
	Min, Max	0, 67	0, 11	0, 78	-22, 22

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	25.4 (36.69)	1.6 (7.67)	11.1 (15.71)	-12.7 (16.27)
	Median	0.0	0.0	0.0	-11.1
	Q1, Q3	0.0, 77.8	0.0, 11.1	0.0, 33.3	-22.2, 0.0
	Min, Max	0, 78	-11, 11	0, 33	-44, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (46.70)	8.3 (18.98)	18.5 (30.36)	-9.3 (25.74)
	Median	50.0	5.6	5.6	-11.1
	Q1, Q3	11.1, 88.9	-5.6, 22.2	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 100	-11, 33	0, 78	-44, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	40.7 (52.51)	-11.1 (50.92)	33.3 (15.71)	0.0 (11.11)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	33.3, 33.3	-11.1, 11.1
	Min, Max	0, 100	-67, 33	11, 56	-11, 11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (11.11)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-22.2, 0.0
	Min, Max	0, 33	-56, 0	11, 33	-22, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	29.6 (33.95)	-22.2 (38.49)	33.3 (31.43)	0.0 (15.71)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	11.1, 55.6	-11.1, 11.1
	Min, Max	0, 67	-67, 0	11, 56	-11, 11
Cycle 18	n	3	3	3	3
	Mean (SD)	37.0 (39.02)	-14.8 (16.97)	25.9 (16.97)	-7.4 (6.42)
	Median	33.3	-11.1	22.2	-11.1
	Q1, Q3	0.0, 77.8	-33.3, 0.0	11.1, 44.4	-11.1, 0.0
	Min, Max	0, 78	-33, 0	11, 44	-11, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (0.00)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-11.1, -11.1
	Min, Max	0, 33	-56, 0	11, 33	-11, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (22.22)	-29.6 (25.66)	37.0 (6.42)	3.7 (6.42)
	Median	22.2	-44.4	33.3	0.0
	Q1, Q3	0.0, 44.4	-44.4, 0.0	33.3, 44.4	0.0, 11.1
	Min, Max	0, 44	-44, 0	33, 44	0, 11
Cycle 24	n	2	2	3	3
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	37.0 (12.83)	3.7 (16.97)
	Median	11.1	-22.2	44.4	0.0
	Q1, Q3	0.0, 22.2	-44.4, 0.0	22.2, 44.4	-11.1, 22.2
	Min, Max	0, 22	-44, 0	22, 44	-11, 22

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	25.9 (16.97)	-7.4 (6.42)
	Median	11.1	-22.2	22.2	-11.1
	Q1, Q3	0.0, 22.2	-44.4, 0.0	11.1, 44.4	-11.1, 0.0
	Min, Max	0, 22	-44, 0	11, 44	-11, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	38.9 (7.86)	5.6 (7.86)
	Median	16.7	-16.7	38.9	5.6
	Q1, Q3	0.0, 33.3	-33.3, 0.0	33.3, 44.4	0.0, 11.1
	Min, Max	0, 33	-33, 0	33, 44	0, 11
Cycle 30	n	2	2	2	2
	Mean (SD)	33.3 (0.00)	-44.4 (15.71)	27.8 (23.57)	-5.6 (7.86)
	Median	33.3	-44.4	27.8	-5.6
	Q1, Q3	33.3, 33.3	-55.6, -33.3	11.1, 44.4	-11.1, 0.0
	Min, Max	33, 33	-56, -33	11, 44	-11, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	40.7 (52.51)	-11.1 (29.40)	22.2 (NE)	0.0 (NE)
	Median	22.2	0.0	22.2	0.0
	Q1, Q3	0.0, 100.0	-44.4, 11.1	22.2, 22.2	0.0, 0.0
	Min, Max	0, 100	-44, 11	22, 22	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	37.0 (39.02)	-14.8 (16.97)	33.3 (NE)	11.1 (NE)
	Median	33.3	-11.1	33.3	11.1
	Q1, Q3	0.0, 77.8	-33.3, 0.0	33.3, 33.3	11.1, 11.1
	Min, Max	0, 78	-33, 0	33, 33	11, 11
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	22.2 (NE)	0.0 (NE)
	Median	0.0	0.0	22.2	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	22.2, 22.2	0.0, 0.0
	Min, Max	0, 0	0, 0	22, 22	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	44.4 (NE)	-44.4 (NE)	22.2 (NE)	0.0 (NE)
	Median	44.4	-44.4	22.2	0.0
	Q1, Q3	44.4, 44.4	-44.4, -44.4	22.2, 22.2	0.0, 0.0
	Min, Max	44, 44	-44, -44	22, 22	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-22.2 (NE)	33.3 (NE)	11.1 (NE)
	Median	66.7	-22.2	33.3	11.1
	Q1, Q3	66.7, 66.7	-22.2, -22.2	33.3, 33.3	11.1, 11.1
	Min, Max	67, 67	-22, -22	33, 33	11, 11
Cycle 48	n	1	1	0	0
	Mean (SD)	77.8 (NE)	-11.1 (NE)		
	Median	77.8	-11.1		
	Q1, Q3	77.8, 77.8	-11.1, -11.1		
	Min, Max	78, 78	-11, -11		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	55.6 (NE)	-33.3 (NE)		
	Median	55.6	-33.3		
	Q1, Q3	55.6, 55.6	-33.3, -33.3		
	Min, Max	56, 56	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-22.2 (NE)		
	Median	66.7	-22.2		
	Q1, Q3	66.7, 66.7	-22.2, -22.2		
	Min, Max	67, 67	-22, -22		
Cycle 56	n	1	1	0	0
	Mean (SD)	44.4 (NE)	-44.4 (NE)		
	Median	44.4	-44.4		
	Q1, Q3	44.4, 44.4	-44.4, -44.4		
	Min, Max	44, 44	-44, -44		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	44.4 (NE)	-44.4 (NE)		
	Median	44.4	-44.4		
	Q1, Q3	44.4, 44.4	-44.4, -44.4		
	Min, Max	44, 44	-44, -44		
Cycle 60	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-55.6 (NE)		
	Median	33.3	-55.6		
	Q1, Q3	33.3, 33.3	-55.6, -55.6		
	Min, Max	33, 33	-56, -56		
Cycle 64	n	1	1	0	0
	Mean (SD)	88.9 (NE)	0.0 (NE)		
	Median	88.9	0.0		
	Q1, Q3	88.9, 88.9	0.0, 0.0		
	Min, Max	89, 89	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	18.5 (14.70)	1.2 (18.79)	41.7 (23.83)	8.3 (16.97)
	Median	22.2	0.0	33.3	5.6
	Q1, Q3	0.0, 33.3	0.0, 11.1	27.8, 66.7	0.0, 22.2
	Min, Max	0, 33	-33, 22	0, 89	-22, 33
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	38.0 (36.22)	13.9 (13.50)	58.8 (26.58)	25.5 (15.60)
	Median	22.2	11.1	55.6	33.3
	Q1, Q3	11.1, 61.1	5.6, 22.2	44.4, 77.8	22.2, 33.3
	Min, Max	0, 100	-11, 33	11, 100	0, 56

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	5.6 (10.86)		8.8 (16.79)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 8.3		0.0, 16.7	
	Min, Max	0, 33		0, 50	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (13.15)	20.0 (20.12)	10.0 (13.80)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 17	0, 67	-17, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-1.7 (9.46)	15.3 (20.67)	12.5 (23.70)
	Median	0.0	0.0	8.3	8.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 25.0	0.0, 25.0
	Min, Max	0, 17	-17, 17	0, 67	-17, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (18.84)	3.7 (13.89)	11.1 (12.97)	8.3 (15.08)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 50	-17, 33	0, 33	-17, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (12.60)	2.1 (13.91)	16.7 (19.72)	13.6 (22.13)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-17, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	7.1 (13.11)	4.8 (12.60)	22.2 (18.63)	18.5 (21.15)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 50	-17, 50

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (19.25)	7.1 (8.91)	2.4 (15.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	-16.7, 16.7
	Min, Max	0, 33	-33, 33	0, 17	-17, 17
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-4.2 (28.46)	5.6 (13.61)	0.0 (10.54)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-25.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	-17, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (25.46)	10.0 (22.36)	3.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 17	0, 50	-17, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	16.7 (23.57)	8.3 (11.79)
	Median	0.0	0.0	16.7	8.3
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (9.62)	5.6 (9.62)
	Median	0.0	-8.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 17	0, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	16.7 (16.67)	11.1 (9.62)
	Median	0.0	-8.3	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 33	0, 17
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	16.7 (23.57)	8.3 (11.79)
	Median	0.0	-8.3	16.7	8.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 33	0, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	8.3 (11.79)	0.0 (0.00)
	Median	0.0	-25.0	8.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 16.7	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 17	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	16.7 (NE)	16.7 (NE)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	16.7, 16.7	16.7, 16.7
	Min, Max	0, 0	0, 0	17, 17	17, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-33.3 (NE)	16.7 (NE)	16.7 (NE)
	Median	0.0	-33.3	16.7	16.7
	Q1, Q3	0.0, 0.0	-33.3, -33.3	16.7, 16.7	16.7, 16.7
	Min, Max	0, 0	-33, -33	17, 17	17, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-33.3 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -33	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 60	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	5.6 (16.67)	3.7 (18.22)	15.6 (15.48)	6.3 (21.84)
	Median	0.0	0.0	16.7	8.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-17, 50	0, 33	-50, 33
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	11.1 (20.52)	5.6 (16.41)	35.3 (19.44)	26.5 (18.69)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 8.3	16.7, 50.0	16.7, 33.3
	Min, Max	0, 50	-17, 50	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	18.1 (28.83)		24.5 (31.25)	
	Median	0.0		16.7	
	Q1, Q3	0.0, 25.0		0.0, 33.3	
	Min, Max	0, 83		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.0 (11.25)	-13.3 (26.99)	24.4 (33.25)	1.1 (29.19)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 0.0
	Min, Max	0, 33	-83, 0	0, 100	-50, 83
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-15.0 (24.15)	26.4 (27.02)	5.6 (32.05)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-8.3, 16.7
	Min, Max	0, 17	-67, 0	0, 83	-50, 83

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	13.0 (28.60)	-7.4 (12.11)	20.8 (23.70)	0.0 (26.59)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 83	-33, 0	0, 83	-50, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	6.3 (17.68)	-8.3 (12.60)	21.2 (24.82)	6.1 (22.70)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-33, 0	0, 83	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (16.67)	20.4 (24.69)	5.6 (25.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-33, 50

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.13)	-11.9 (24.93)	7.1 (13.11)	2.4 (20.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-67, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (9.62)	-16.7 (33.33)	11.1 (27.22)	5.6 (32.77)
	Median	8.3	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 17	-67, 0	0, 67	-33, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	16.7 (28.87)	-16.7 (60.09)	20.0 (21.73)	13.3 (21.73)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 50.0	-83.3, 33.3	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-83, 33	0, 50	0, 50

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (16.67)	16.7 (16.67)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (9.62)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-17, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	27.8 (48.11)	-5.6 (9.62)	22.2 (9.62)	22.2 (9.62)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 83.3	-16.7, 0.0	16.7, 33.3	16.7, 33.3
	Min, Max	0, 83	-17, 0	17, 33	17, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	-8.3	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-33.3 (23.57)	25.0 (11.79)	25.0 (11.79)
	Median	16.7	-33.3	25.0	25.0
	Q1, Q3	0.0, 33.3	-50.0, -16.7	16.7, 33.3	16.7, 33.3
	Min, Max	0, 33	-50, -17	17, 33	17, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	0.0 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-17, 17	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	16.7 (28.87)	-16.7 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 50	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-50.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	-50.0	33.3	33.3
	Q1, Q3	33.3, 33.3	-50.0, -50.0	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	-50, -50	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-50.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	-50.0	33.3	33.3
	Q1, Q3	33.3, 33.3	-50.0, -50.0	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	-50, -50	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-33.3 (NE)		
	Median	50.0	-33.3		
	Q1, Q3	50.0, 50.0	-33.3, -33.3		
	Min, Max	50, 50	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	83.3 (NE)	0.0 (NE)		
	Median	83.3	0.0		
	Q1, Q3	83.3, 83.3	0.0, 0.0		
	Min, Max	83, 83	0, 0		
Cycle 60	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-66.7 (NE)		
	Median	16.7	-66.7		
	Q1, Q3	16.7, 16.7	-66.7, -66.7		
	Min, Max	17, 17	-67, -67		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	7.4 (12.11)	-3.7 (23.24)	36.5 (32.33)	11.5 (29.01)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	8.3, 66.7	0.0, 33.3
	Min, Max	0, 33	-50, 33	0, 100	-33, 67
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	26.4 (32.14)	8.3 (19.46)	50.0 (30.05)	25.5 (32.87)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 41.7	0.0, 25.0	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 83

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		15.7 (26.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	24.4 (26.63)	11.1 (20.57)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (23.57)	8.3 (23.57)	12.1 (22.47)	3.0 (10.05)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	14.8 (24.22)	3.7 (11.11)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	25.0 (31.91)	11.1 (27.22)	5.6 (13.61)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	13.3 (18.26)	6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (33.33)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 33.3
	Min, Max	0, 33	0, 33	0, 33	-33, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	16.7	16.7	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	66.7 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	66.7	33.3	33.3
	Q1, Q3	66.7, 66.7	66.7, 66.7	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	67, 67	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	100.0 (NE)		
	Median	100.0	100.0		
	Q1, Q3	100.0, 100.0	100.0, 100.0		
	Min, Max	100, 100	100, 100		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 60	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	11.1 (16.67)	11.1 (16.67)	29.2 (29.50)	12.5 (20.64)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	16.7 (30.15)	16.7 (30.15)	39.2 (26.97)	23.5 (22.87)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (35.77)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 50.0		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	16.7 (28.33)	-10.0 (16.10)	28.9 (30.52)	6.7 (31.37)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 100	-67, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	13.3 (17.21)	-13.3 (39.13)	25.0 (25.13)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	11.1 (16.67)	-18.5 (33.79)	16.7 (17.41)	2.8 (22.29)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	20.8 (24.80)	-12.5 (24.80)	9.1 (21.56)	0.0 (21.08)
	Median	16.7	-16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	-9.5 (16.27)	11.1 (16.67)	3.7 (20.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	28.6 (40.50)	-9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-41.7 (41.94)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-66.7, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-100, 0	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	13.3 (29.81)	6.7 (14.91)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	44.4 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	66.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-44.4 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	-22.2 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	33.3	-33.3	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	33.3 (33.33)	22.2 (38.49)
	Median	16.7	-16.7	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	22.2 (19.25)	11.1 (19.25)
	Median	16.7	-16.7	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 33	0, 33
Cycle 28	n	2	2	2	2
	Mean (SD)	33.3 (47.14)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	33.3 (0.00)	-50.0 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	-50.0	16.7	0.0
	Q1, Q3	33.3, 33.3	-66.7, -33.3	0.0, 33.3	0.0, 0.0
	Min, Max	33, 33	-67, -33	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (33.33)	-22.2 (19.25)	0.0 (NE)	0.0 (NE)
	Median	33.3	-33.3	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	44.4 (50.92)	-11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	-33.3	33.3	33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	-33, -33	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	-33.3	33.3	33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	-33, -33	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 60	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	22.2 (33.33)	3.7 (20.03)	25.0 (31.03)	2.1 (25.73)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-16.7, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 33
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	36.1 (36.12)	13.9 (17.16)	51.0 (29.15)	29.4 (28.58)
	Median	33.3	0.0	66.7	33.3
	Q1, Q3	0.0, 50.0	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	10.0 (22.50)	-10.0 (35.31)	31.1 (34.43)	6.7 (25.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (10.54)	-16.7 (32.39)	19.4 (22.29)	5.6 (27.83)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-11.1 (33.33)	25.0 (20.72)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-12.5 (39.59)	27.3 (25.03)	15.2 (34.52)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	25.9 (22.22)	11.1 (37.27)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 0	0, 67	-67, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	-9.5 (41.79)	14.3 (26.23)	0.0 (38.49)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (16.67)	-8.3 (41.94)	11.1 (27.22)	-5.6 (32.77)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	16.7, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	-22.2 (69.39)	13.3 (29.81)	-6.7 (36.51)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-100, 33	0, 67	-67, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-44.4 (50.92)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-16.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-66.7 (47.14)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-66.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, -33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, -33	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-44.4 (50.92)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	0.0 (NE)	0.0 (NE)
	Median	33.3	-66.7	0.0	0.0
	Q1, Q3	33.3, 33.3	-66.7, -66.7	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	-67, -67	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	-66.7	33.3	33.3
	Q1, Q3	33.3, 33.3	-66.7, -66.7	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	-67, -67	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 60	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 64	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	14.8 (17.57)	3.7 (26.06)	33.3 (32.20)	10.4 (31.55)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	-67, 67
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	38.9 (34.33)	16.7 (26.59)	49.0 (29.15)	27.5 (31.70)
	Median	33.3	16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 67	0, 100	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	19.4 (33.21)		17.6 (31.44)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	3.3 (29.19)	22.2 (34.88)	2.2 (23.46)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (28.11)	0.0 (38.49)	16.7 (17.41)	13.9 (22.29)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 33	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	18.5 (33.79)	0.0 (28.87)	11.1 (16.41)	8.3 (20.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	25.0 (38.83)	16.7 (35.63)	9.1 (15.57)	9.1 (15.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 16.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.8 (17.57)	14.8 (17.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	23.8 (41.79)	14.3 (26.23)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 67	0, 0	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	33.3 (47.14)	16.7 (57.74)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-16.7, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 100	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	0.0 (66.67)	13.3 (29.81)	13.3 (29.81)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 67	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 0	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-11.1 (50.92)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 0	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	16.7 (23.57)	16.7 (23.57)
	Median	16.7	16.7	16.7	16.7
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	16.7 (23.57)	16.7 (23.57)
	Median	16.7	-16.7	16.7	16.7
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 33	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-33.3 (NE)	0.0 (NE)	0.0 (NE)
	Median	33.3	-33.3	0.0	0.0
	Q1, Q3	33.3, 33.3	-33.3, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	-33, -33	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	100.0 (NE)	33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	100.0	33.3	33.3	33.3
	Q1, Q3	100.0, 100.0	33.3, 33.3	33.3, 33.3	33.3, 33.3
	Min, Max	100, 100	33, 33	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	0.0 (NE)		
	Median	66.7	0.0		
	Q1, Q3	66.7, 66.7	0.0, 0.0		
	Min, Max	67, 67	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.7 (NE)	0.0 (NE)		
	Median	66.7	0.0		
	Q1, Q3	66.7, 66.7	0.0, 0.0		
	Min, Max	67, 67	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	7.4 (22.22)	-7.4 (36.43)	25.0 (35.49)	6.3 (25.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 67	-100, 33	0, 100	-33, 67
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	38.9 (42.24)	19.4 (30.01)	37.3 (30.92)	19.6 (29.01)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 83.3	0.0, 33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		7.8 (14.57)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 0.0	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (14.05)	8.9 (15.26)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	10.0 (16.10)	-3.3 (18.92)	22.2 (25.95)	11.1 (21.71)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-33, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (20.03)	11.1 (21.71)	0.0 (14.21)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (15.43)	-4.2 (11.79)	15.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	0.0 (0.00)	18.5 (24.22)	11.1 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (26.23)	0.0 (19.25)	9.5 (25.20)	0.0 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (33.33)	8.3 (16.67)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	11.1 (19.25)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	22.2 (38.49)	11.1 (19.25)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	-33, 0	0, 67	0, 33
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-16.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	33.3 (NE)	0.0 (NE)	0.0 (NE)
	Median	33.3	33.3	0.0	0.0
	Q1, Q3	33.3, 33.3	33.3, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	33, 33	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 60	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	9	9	16	16
	Mean (SD)	7.4 (14.70)	-11.1 (16.67)	4.2 (11.39)	-4.2 (11.39)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	22.2 (25.95)	8.3 (15.08)	23.5 (25.72)	15.7 (20.81)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-2-1-qs-chg-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Global health status / QoL									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	63.19 (29.83)	10.50 (4.57)	17	57.84 (25.08)	3.23 (3.46)	7.27 (-3.30, 17.85)	0.58 (-0.26, 1.43)	0.1680

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.67 (21.84)	-1.63 (2.77)	17	87.06 (14.23)	-10.49 (2.10)	8.86 (2.53, 15.19)	1.22 (0.30, 2.14)	0.0081

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.11 (21.12)	6.19 (4.92)	17	79.41 (26.70)	-5.03 (3.64)	11.22 (-0.36, 22.81)	0.79 (-0.04, 1.63)	0.0570

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	72.92 (27.55)	13.40 (5.91)	17	75.49 (20.08)	0.54 (4.17)	12.87 (-0.63, 26.36)	0.79 (-0.06, 1.64)	0.0606

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Cognitive functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	94.44 (14.79)	0.26 (4.26)	17	78.43 (18.41)	-0.92 (3.17)	1.18 (-9.14, 11.51)	0.11 (-0.80, 1.01)	0.8143

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	83.33 (21.32)	4.87 (5.70)	17	80.39 (17.91)	-7.60 (4.20)	12.47 (-0.85, 25.79)	0.78 (-0.07, 1.63)	0.0650

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	24.07 (31.72)	-6.22 (5.46)	17	33.33 (22.57)	5.60 (4.12)	-11.82 (-24.80, 1.15)	-0.76 (-1.60, 0.09)	0.0714

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	5.56 (10.86)	-3.70 (3.58)	17	8.82 (16.79)	9.08 (2.74)	-12.78 (-20.99, -4.57)	-1.35 (-2.29, -0.41)	0.0038

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	18.06 (28.83)	-14.62 (6.52)	17	24.51 (31.25)	3.66 (4.88)	-18.29 (-33.68, -2.89)	-0.99 (-1.87, -0.12)	0.0226

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-3y.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	2.09 (3.77)	17	15.69 (26.66)	9.88 (2.85)	-7.78 (-16.92, 1.35)	-0.80 (-1.74, 0.15)	0.0907

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Insomnia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (35.77)	-9.34 (4.49)	17	21.57 (31.05)	3.01 (3.58)	-12.35 (-22.58, -2.13)	-1.11 (-2.06, -0.16)	0.0199

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Appetite loss									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	-13.72 (6.40)	17	21.57 (31.05)	2.38 (4.78)	-16.10 (-30.61, -1.59)	-0.97 (-1.88, -0.07)	0.0311

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

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[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Constipation									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	19.44 (33.21)	9.79 (6.80)	17	17.65 (31.44)	8.51 (5.01)	1.28 (-14.59, 17.15)	0.07 (-0.76, 0.90)	0.8684

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Diarrhea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-5.26 (3.06)	17	7.84 (14.57)	3.70 (2.39)	-8.96 (-15.84, -2.08)	-1.22 (-2.19, -0.25)	0.0125

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QoL	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.808 (0.083, 7.837)	0.8539
Physical Functioning	13	2 (15.4)	NR (2.3, NE)	17	8 (47.1)	2.1 (0.9, NE)	0.213 (0.025, 1.787)	0.1173
Role Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.4 (0.7, NE)	0.177 (0.036, 0.879)	0.0198
Emotional Functioning	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	14.7 (2.2, NE)	0.000 (0.000, NE)	0.1326
Cognitive Functioning	13	2 (15.4)	NR (1.4, NE)	17	5 (29.4)	NR (2.2, NE)	0.879 (0.155, 4.997)	0.8846
Social Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.5 (0.8, NE)	0.235 (0.047, 1.179)	0.0586

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-2-1-2-eff-tte-qlq-c30-pop1-3y.rtf

Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Fatigue	13	3 (23.1)	NR (3.7, NE)	17	11 (64.7)	2.1 (0.7, NE)	0.327 (0.079, 1.343)	0.1083
Nausea and Vomiting	13	1 (7.7)	NR (NE, NE)	17	9 (52.9)	4.4 (0.8, NE)	0.135 (0.016, 1.117)	0.0310
Pain	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	NR (2.1, NE)	0.000 (0.000, NE)	0.0539
Dyspnoea	13	3 (23.1)	NR (1.4, NE)	17	4 (23.5)	NR (1.4, NE)	1.714 (0.268, 10.985)	0.5657
Insomnia	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	19.1 (1.4, NE)	0.171 (0.020, 1.450)	0.0687
Appetite Loss	13	2 (15.4)	NR (5.3, NE)	17	8 (47.1)	3.3 (1.4, NE)	0.352 (0.067, 1.851)	0.2032

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Constipation	13	4 (30.8)	37.6 (0.7, NE)	17	7 (41.2)	NR (0.8, NE)	0.634 (0.150, 2.673)	0.5075
Diarrhea	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.1, NE)	0.536 (0.073, 3.928)	0.5358

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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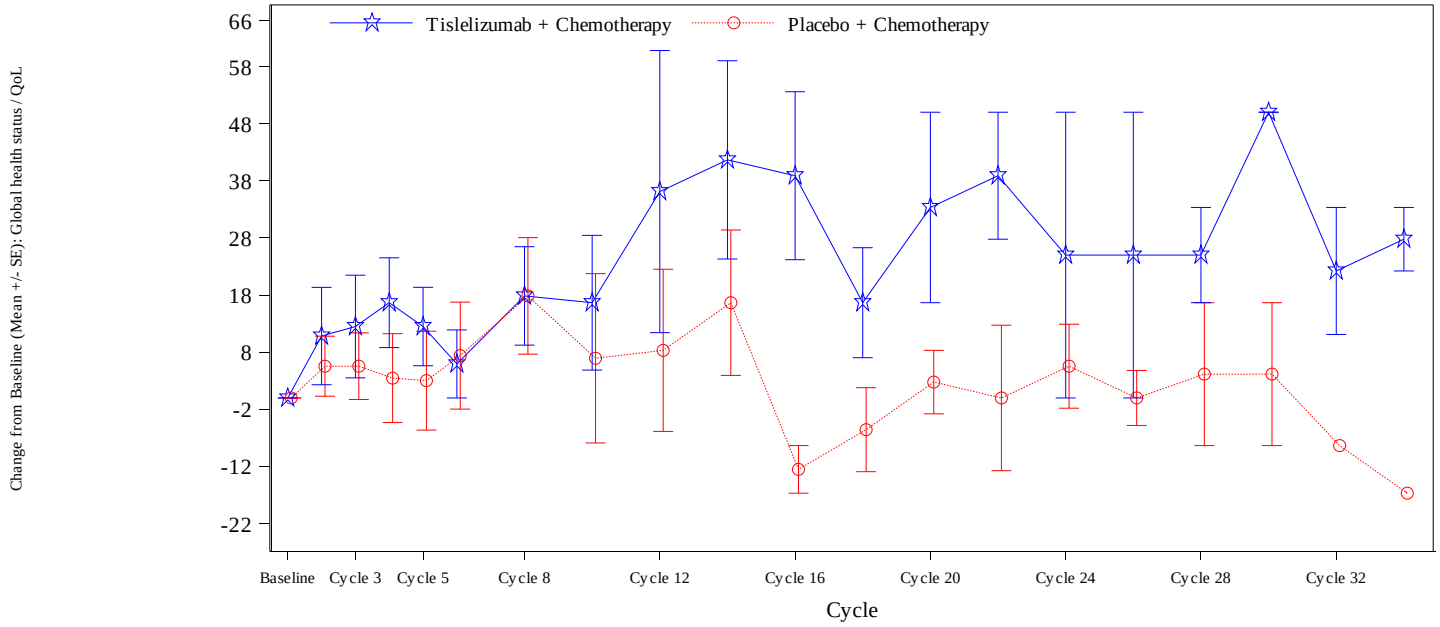
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

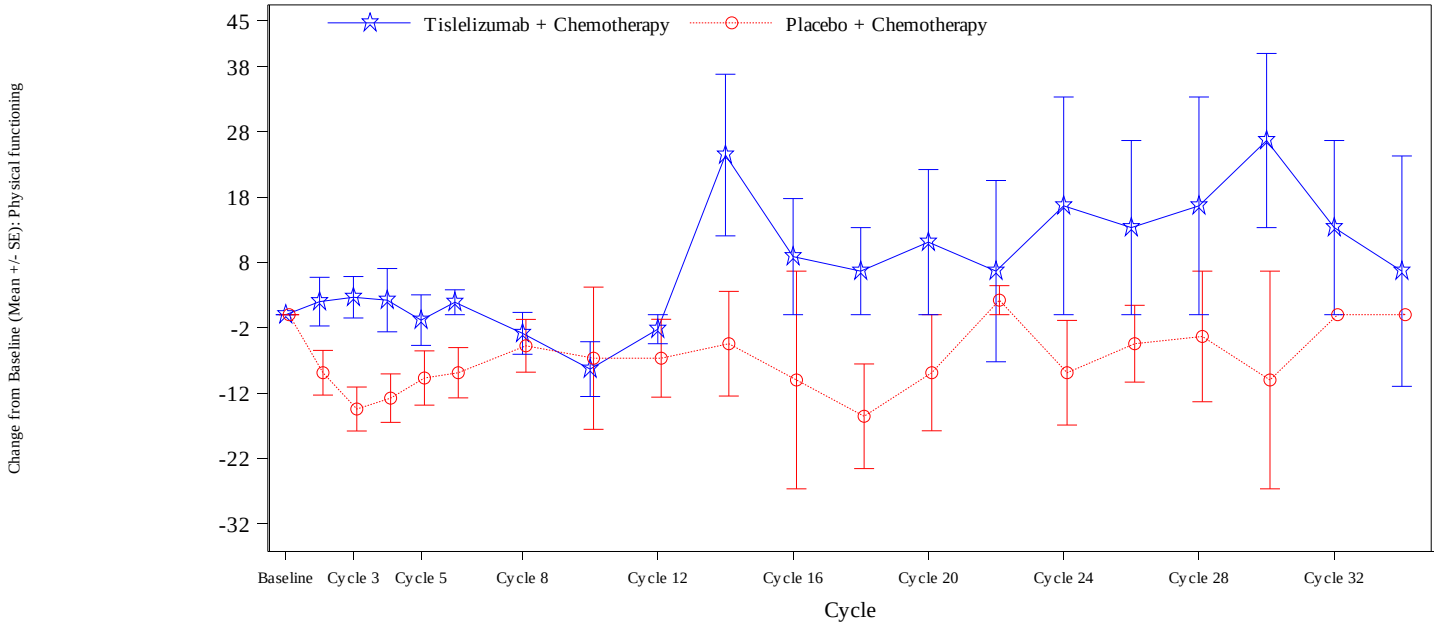


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-1-series-c30-pop1-3y.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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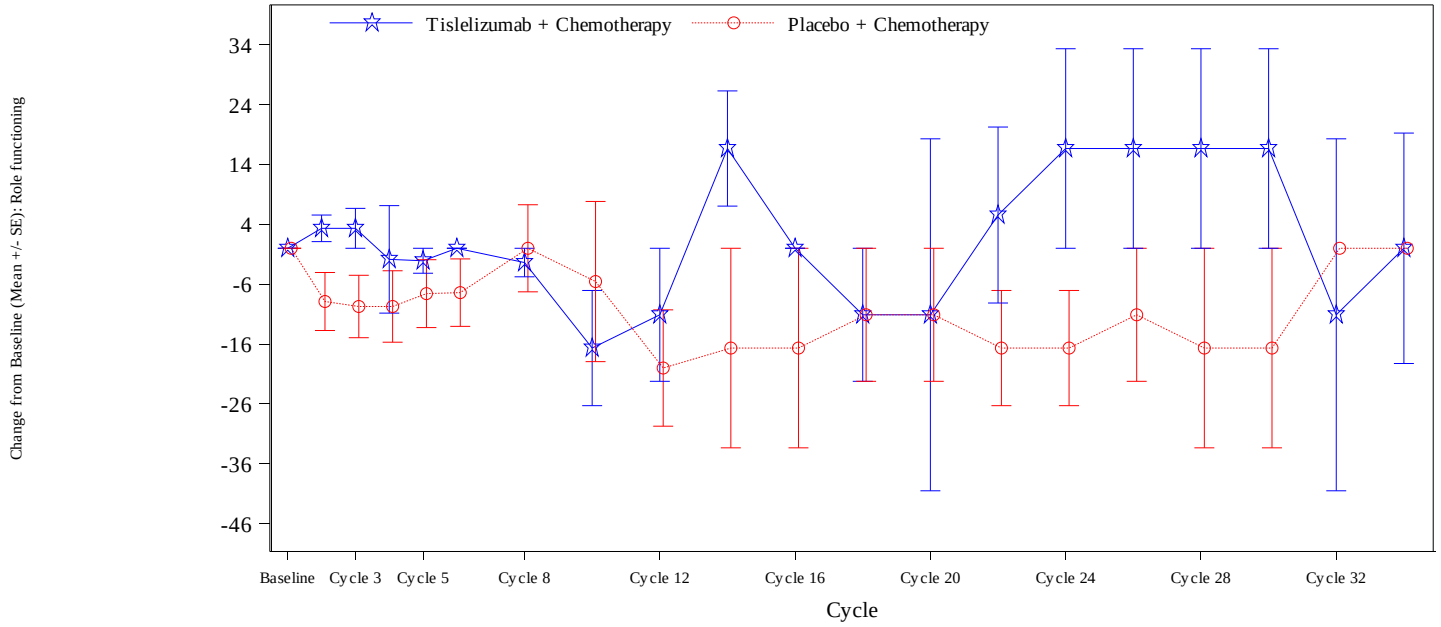

No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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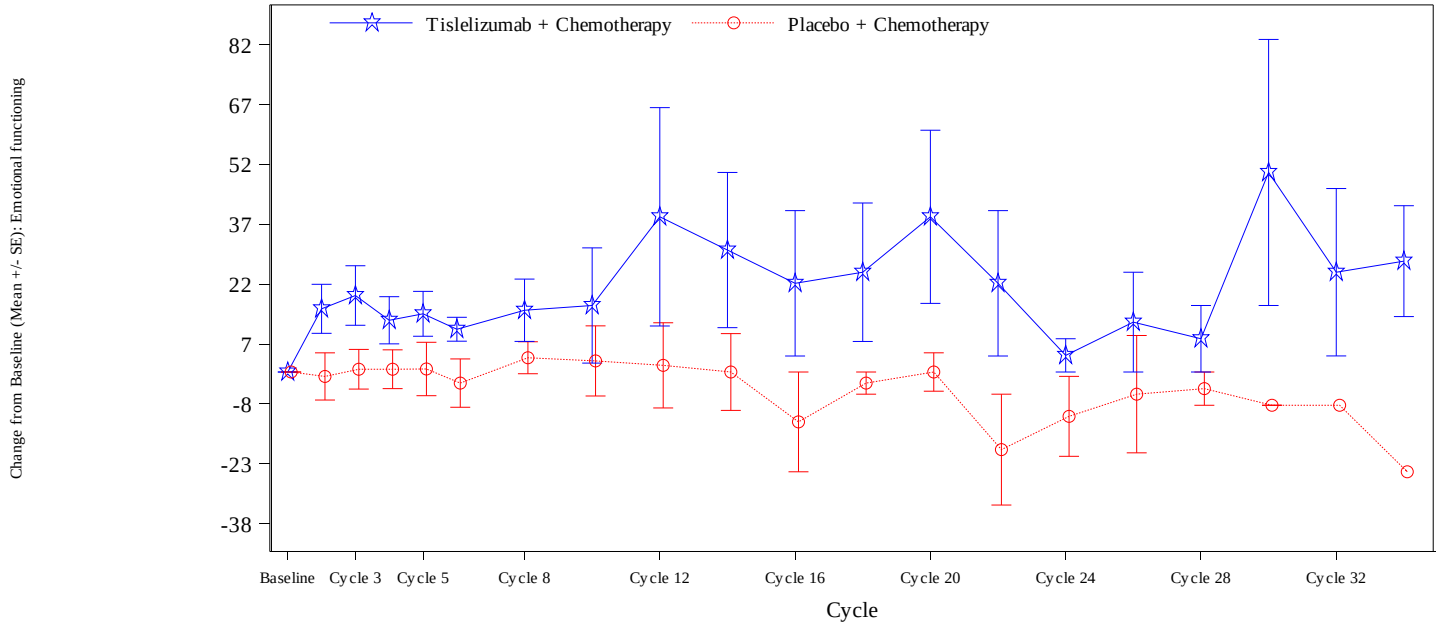
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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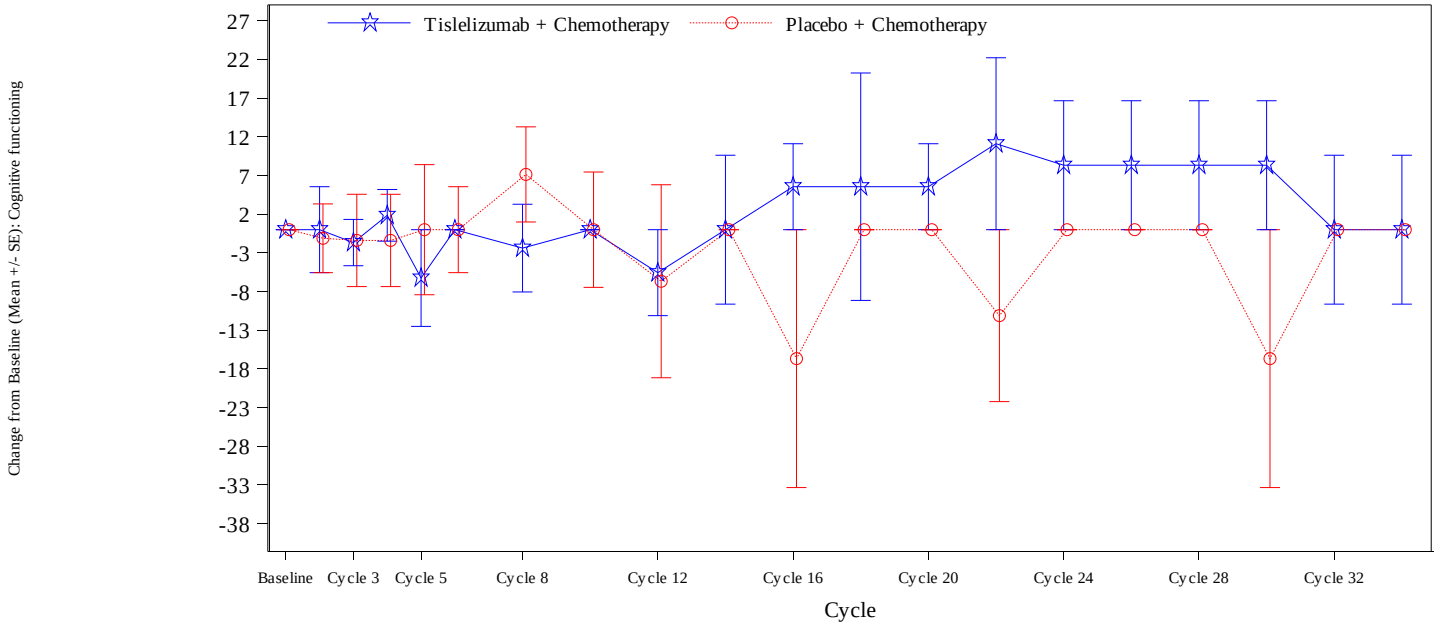

No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
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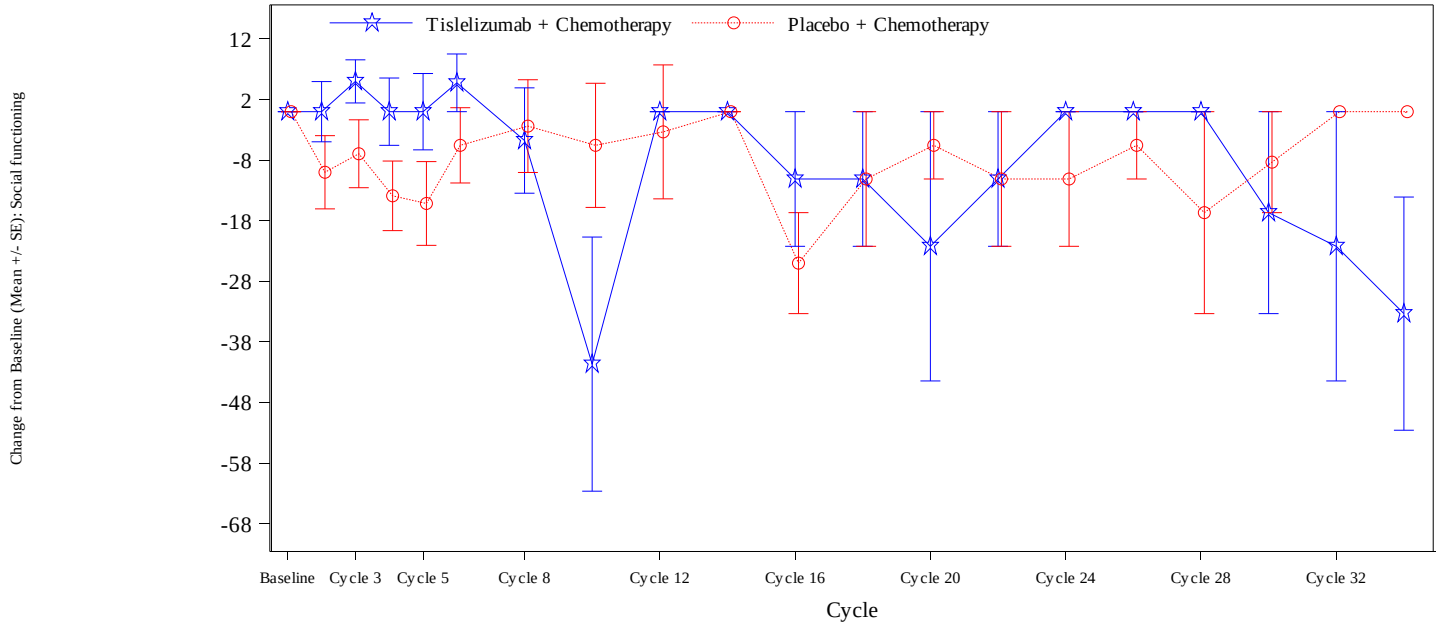
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

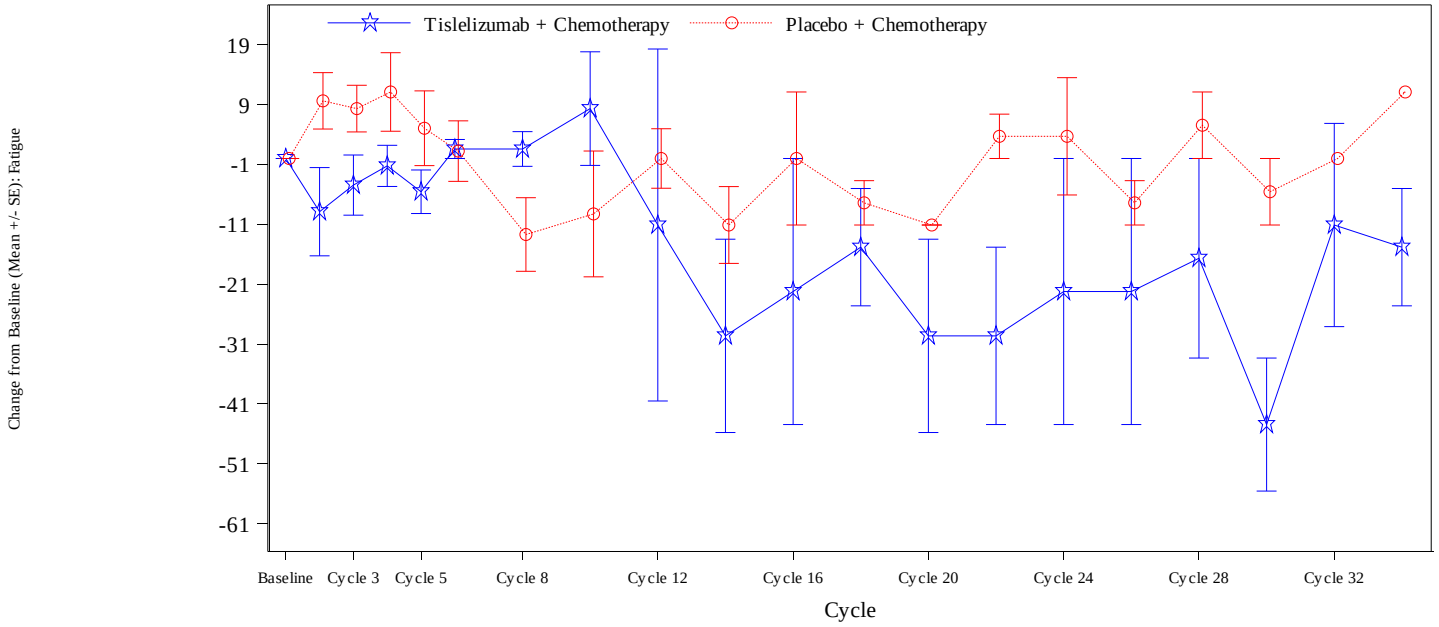


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-1-series-c30-pop1-3y.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

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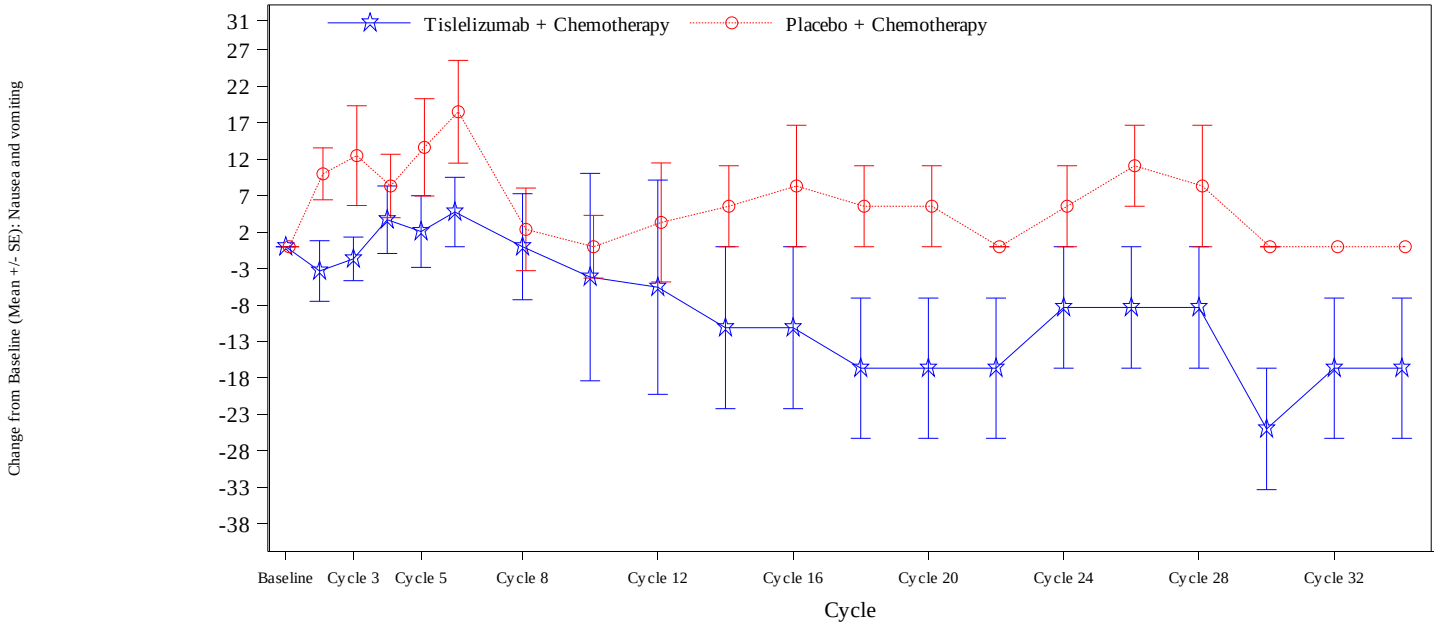

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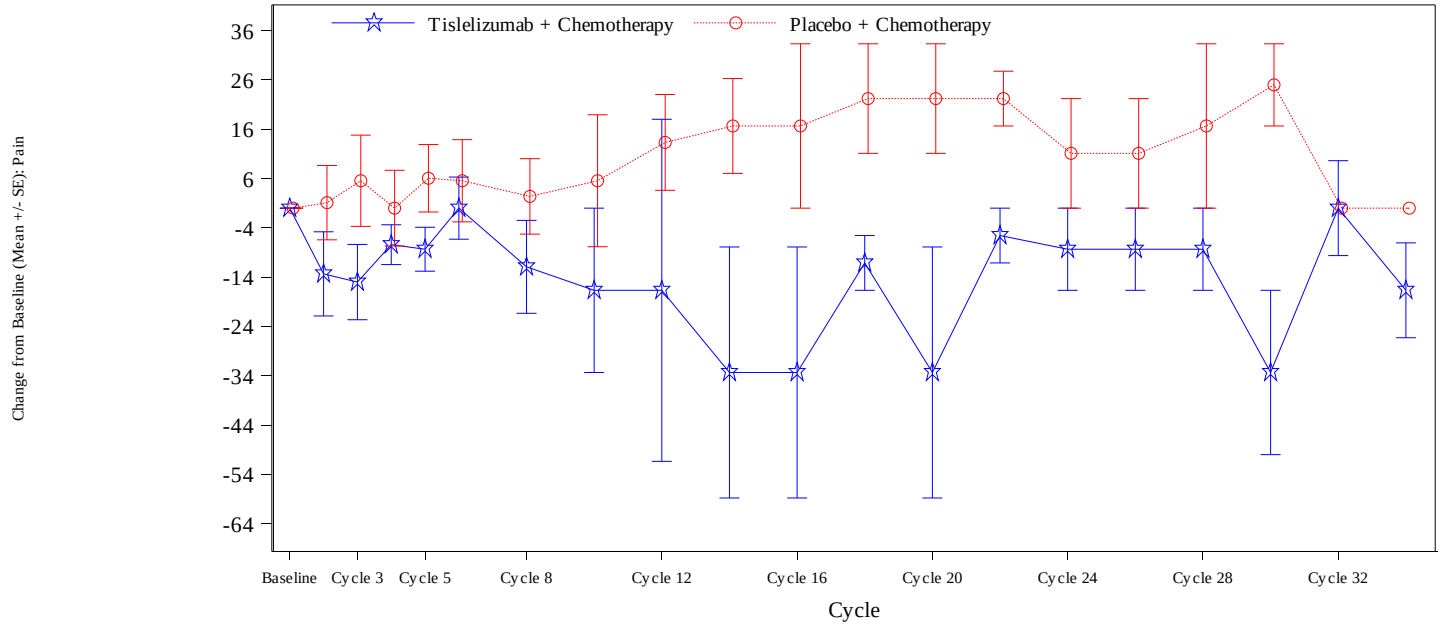

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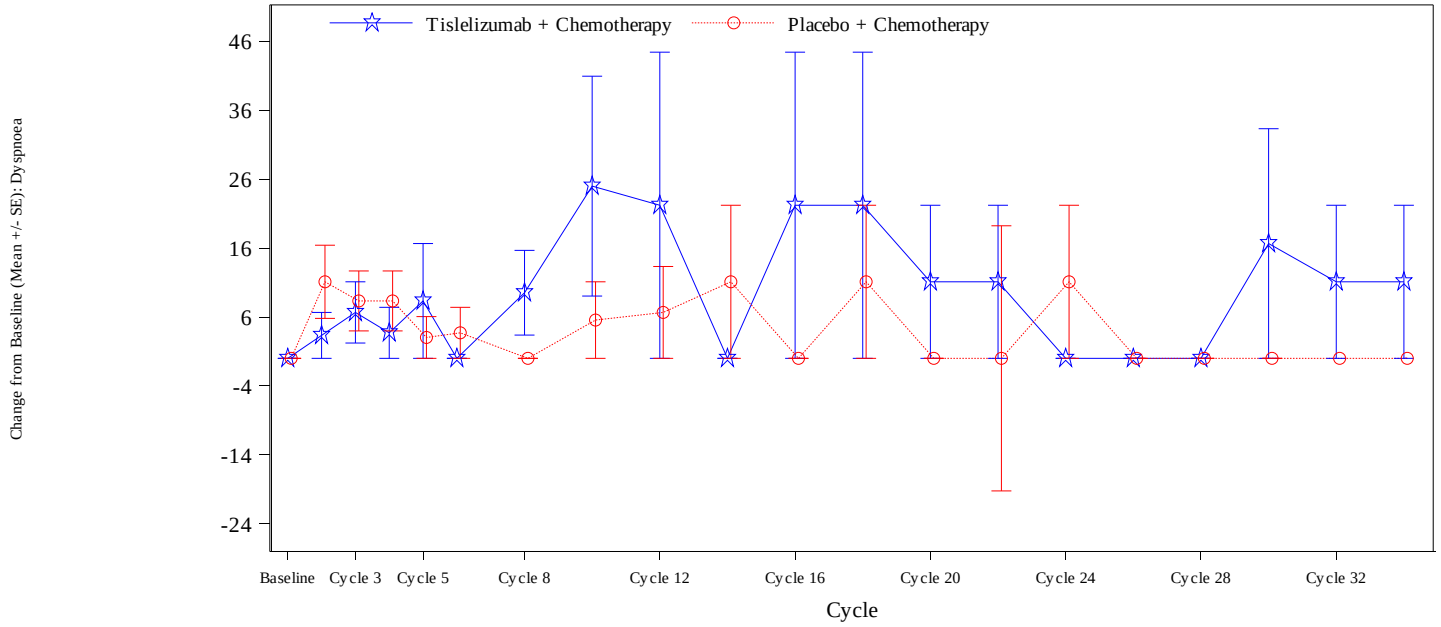

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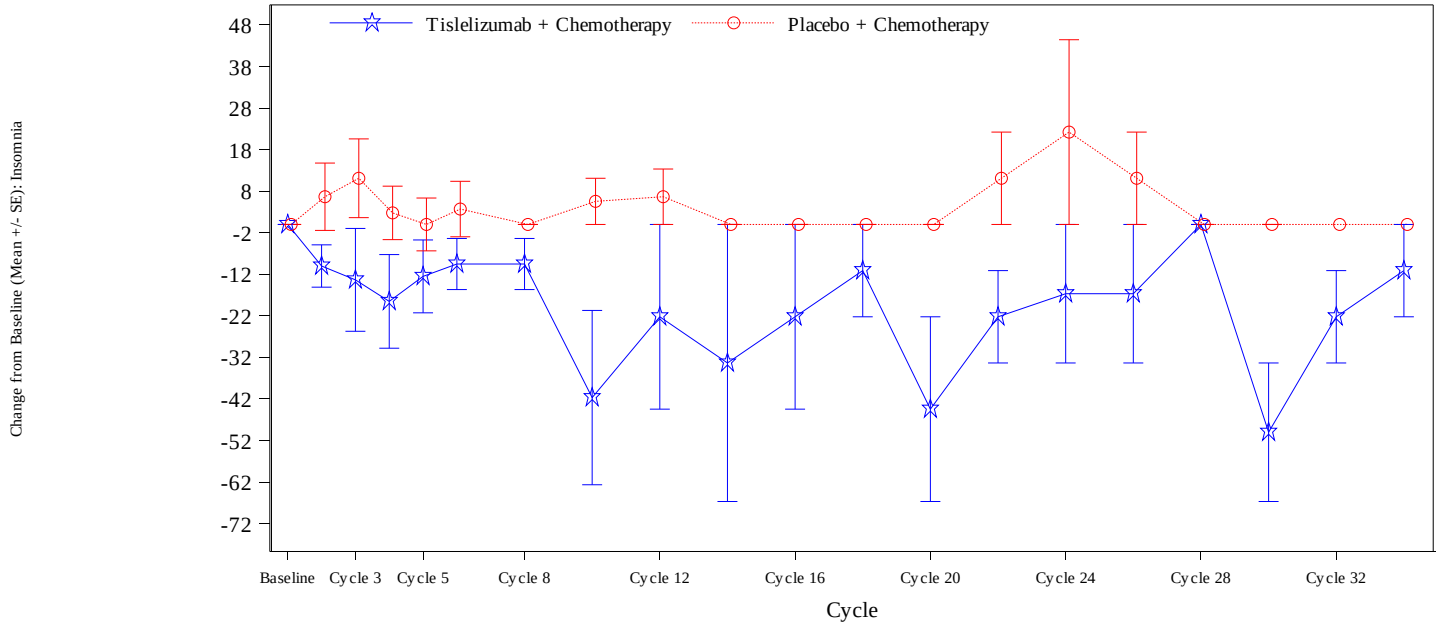

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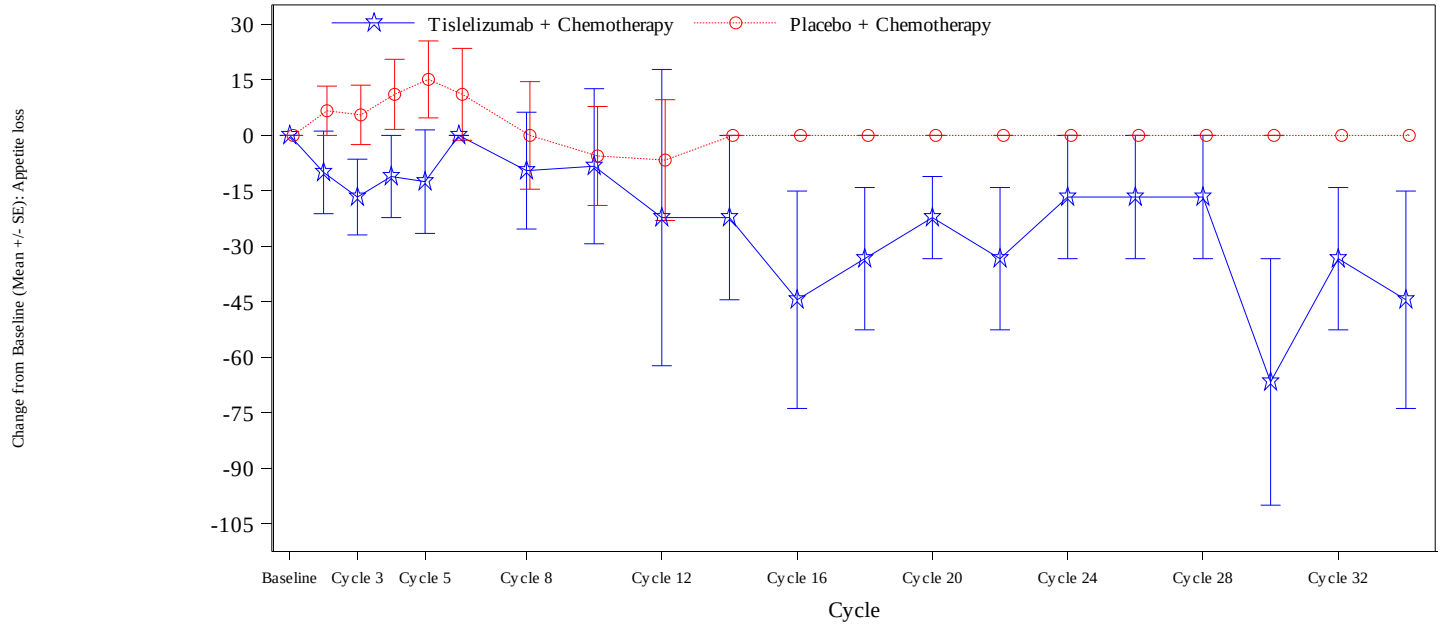

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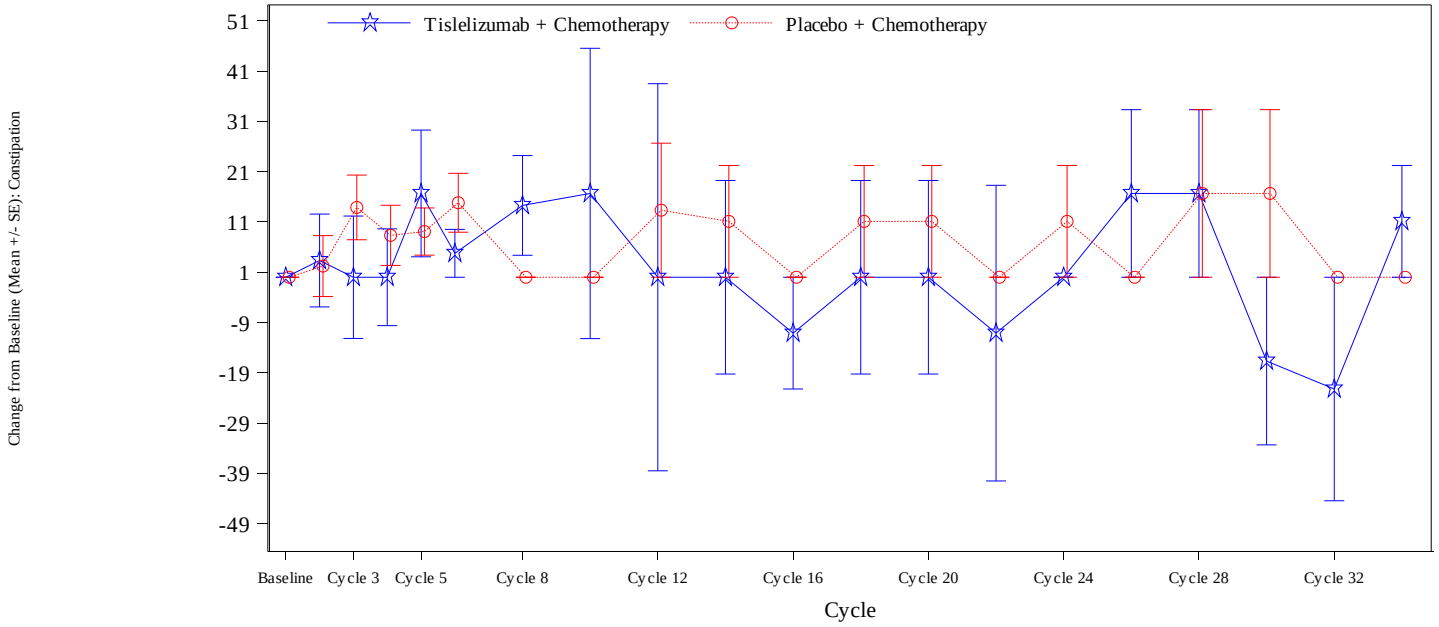

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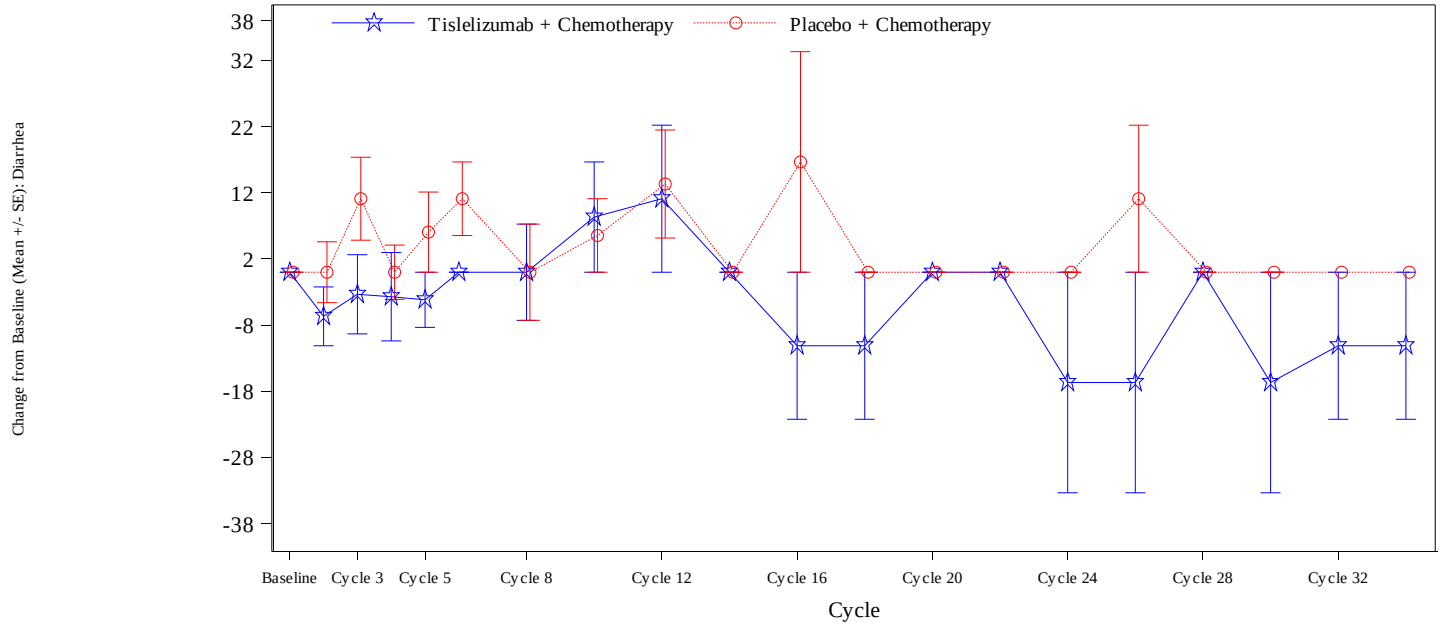

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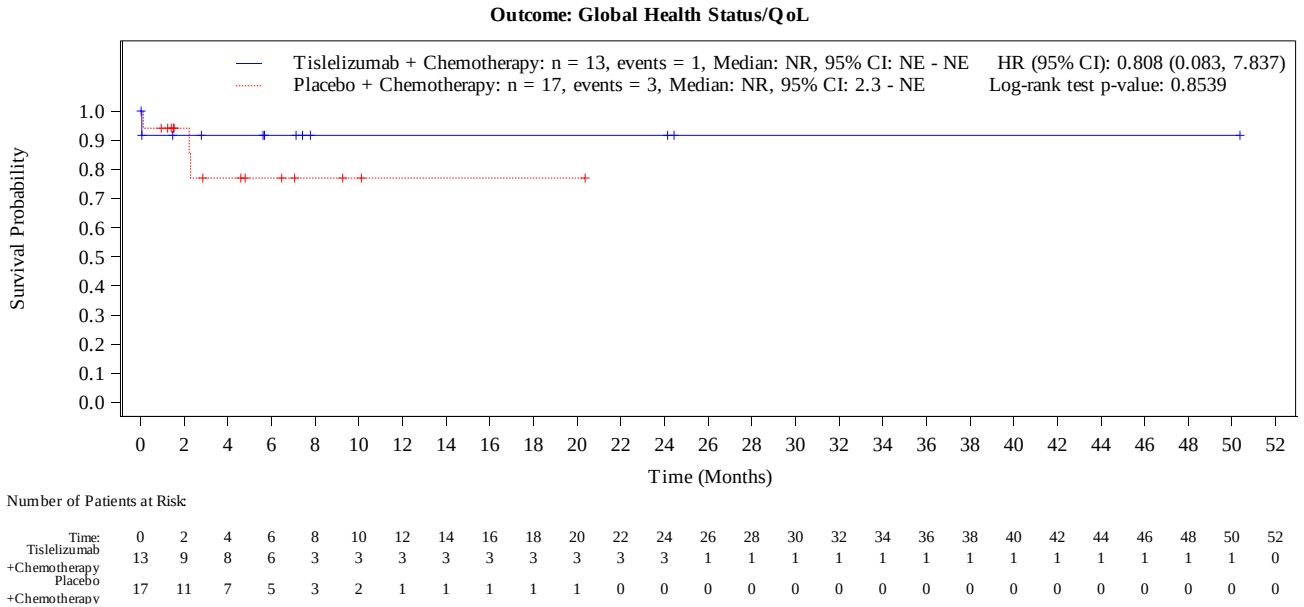
Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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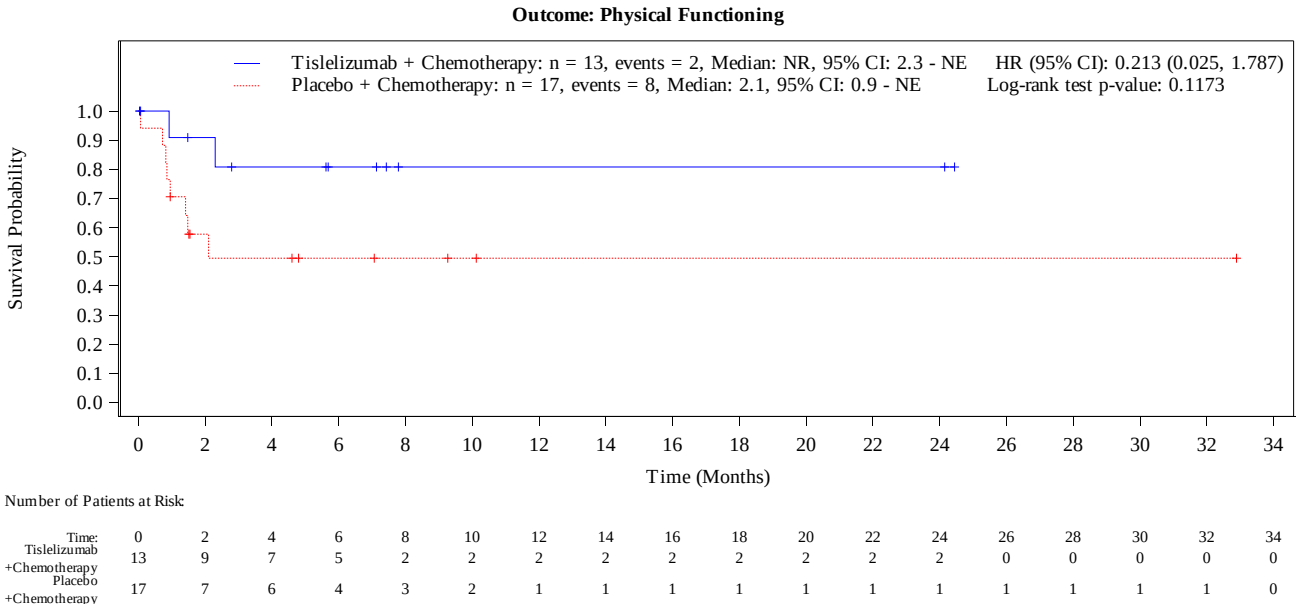

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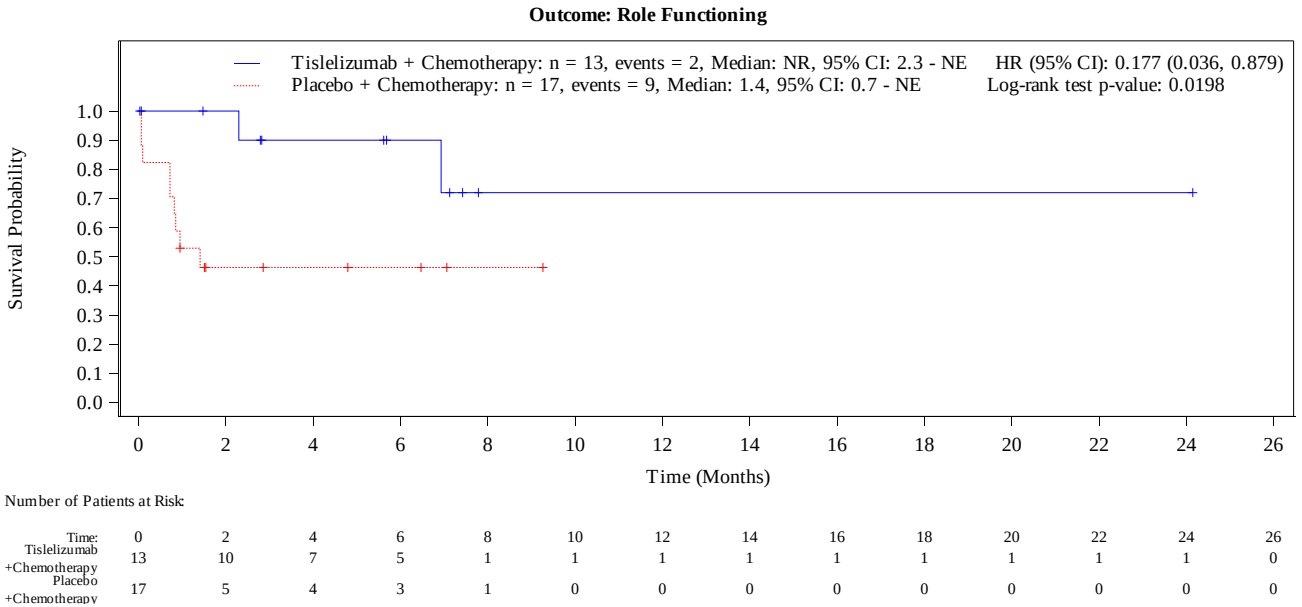

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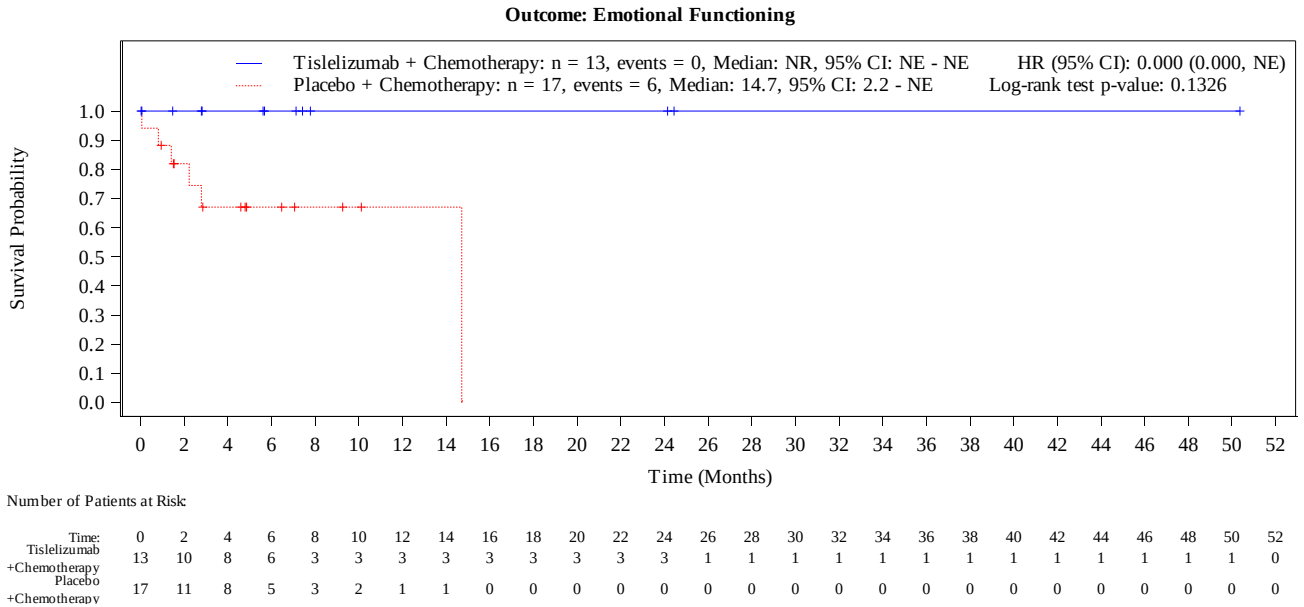

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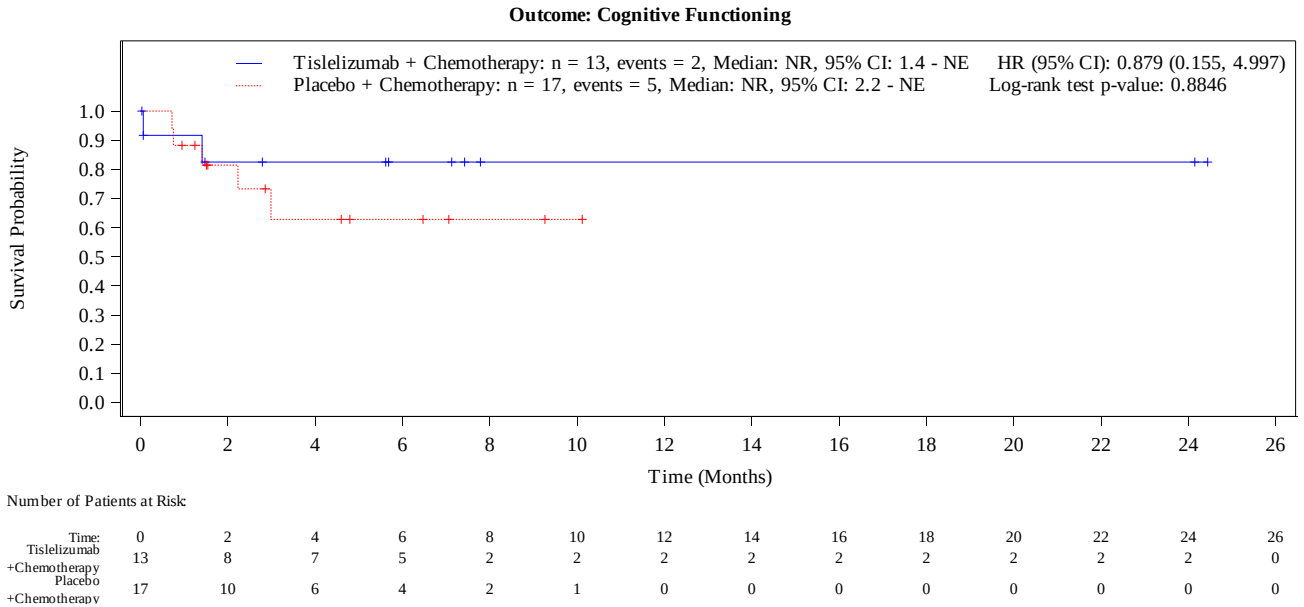

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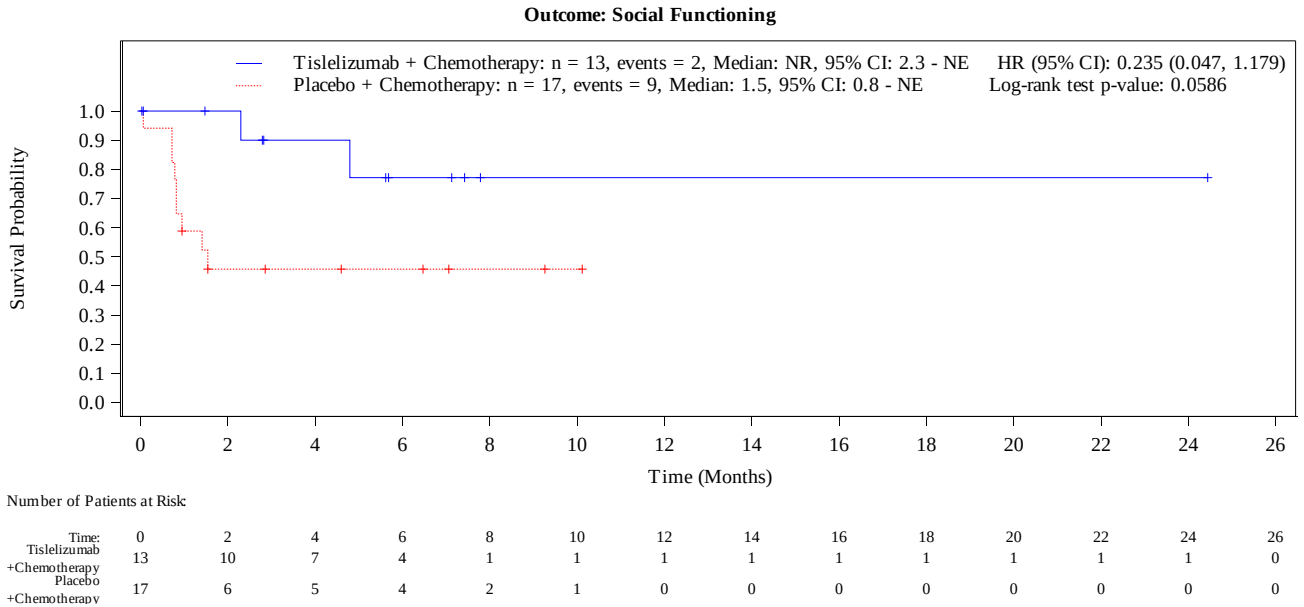

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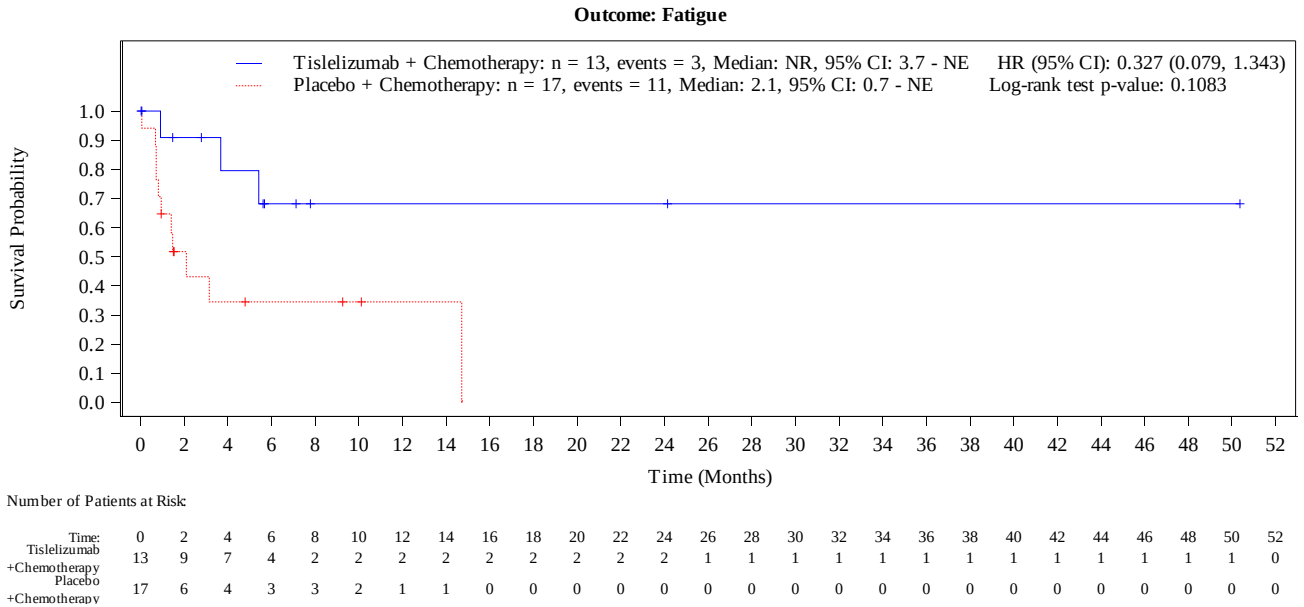

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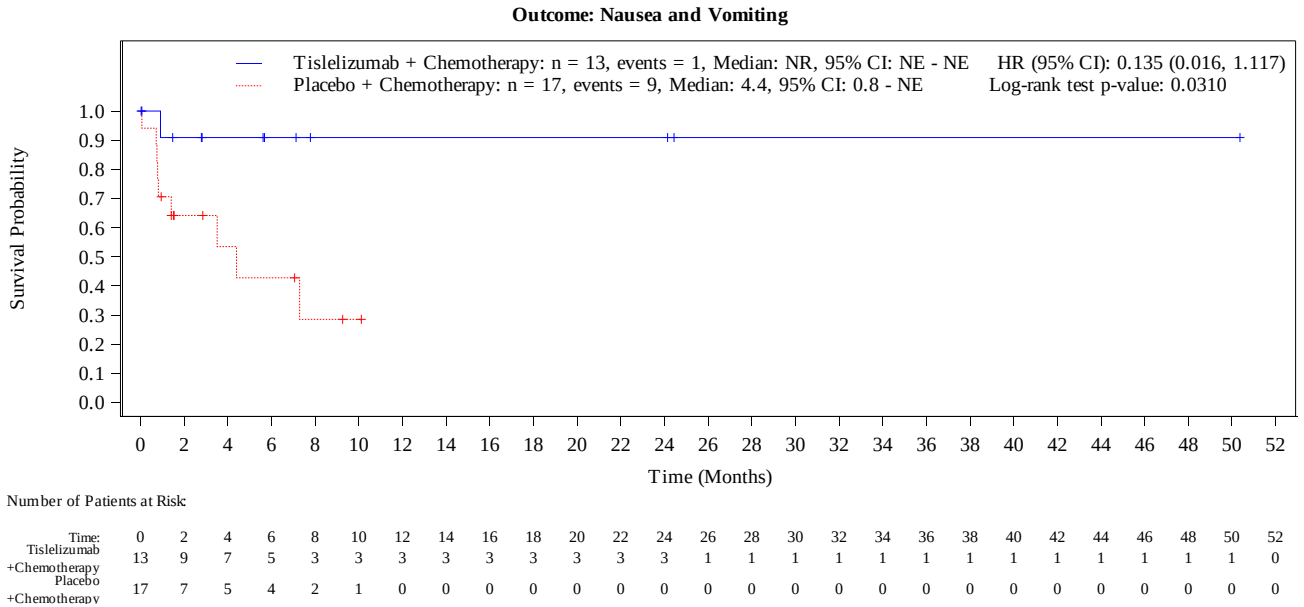

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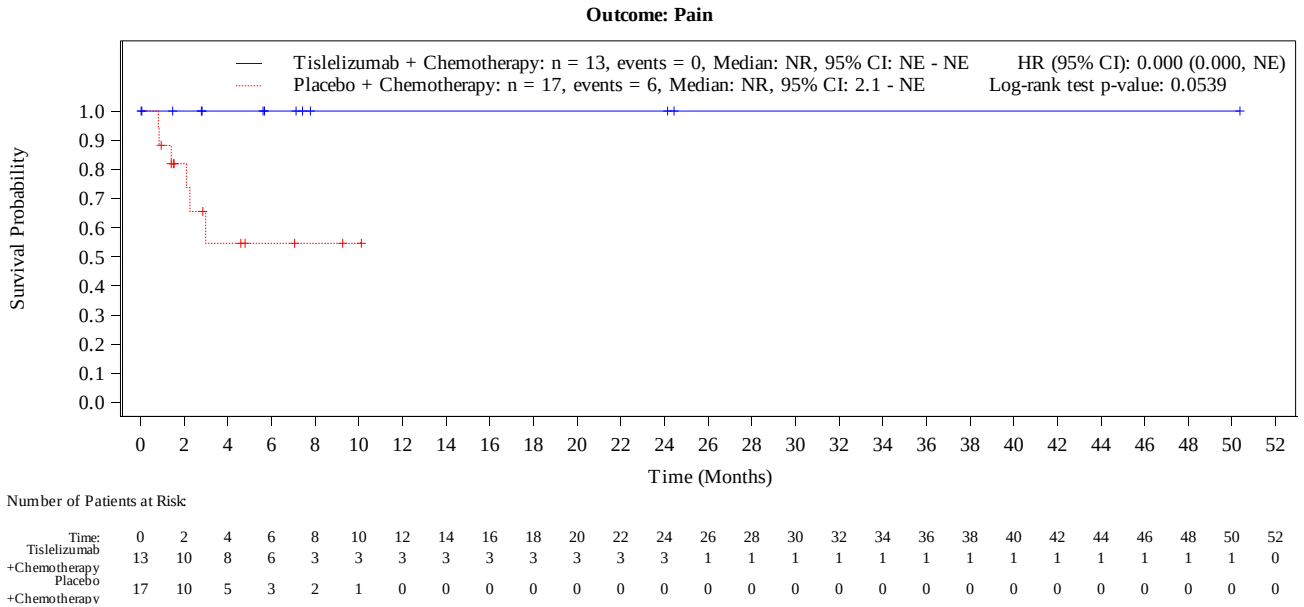
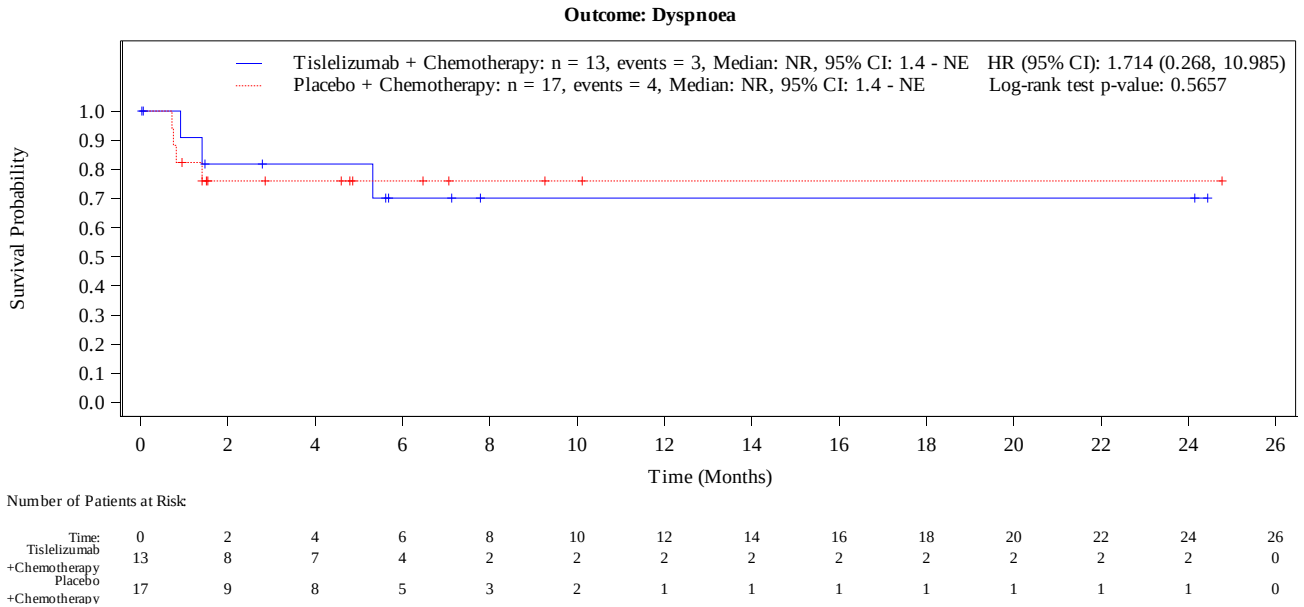
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-3y.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



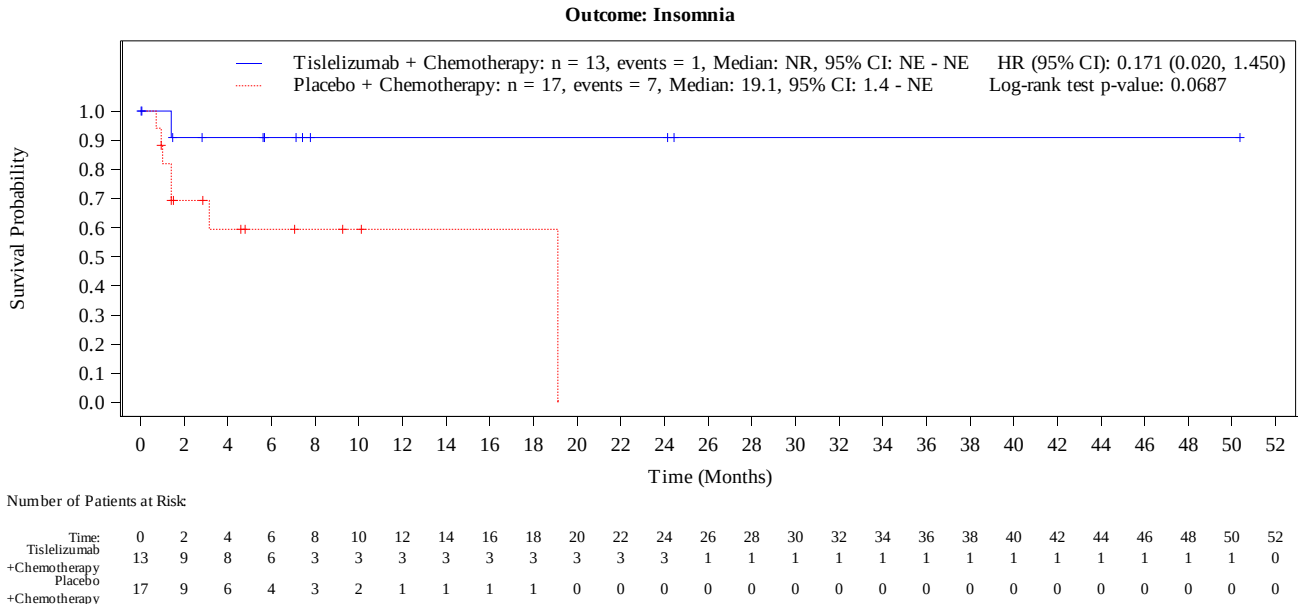
Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-3y.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



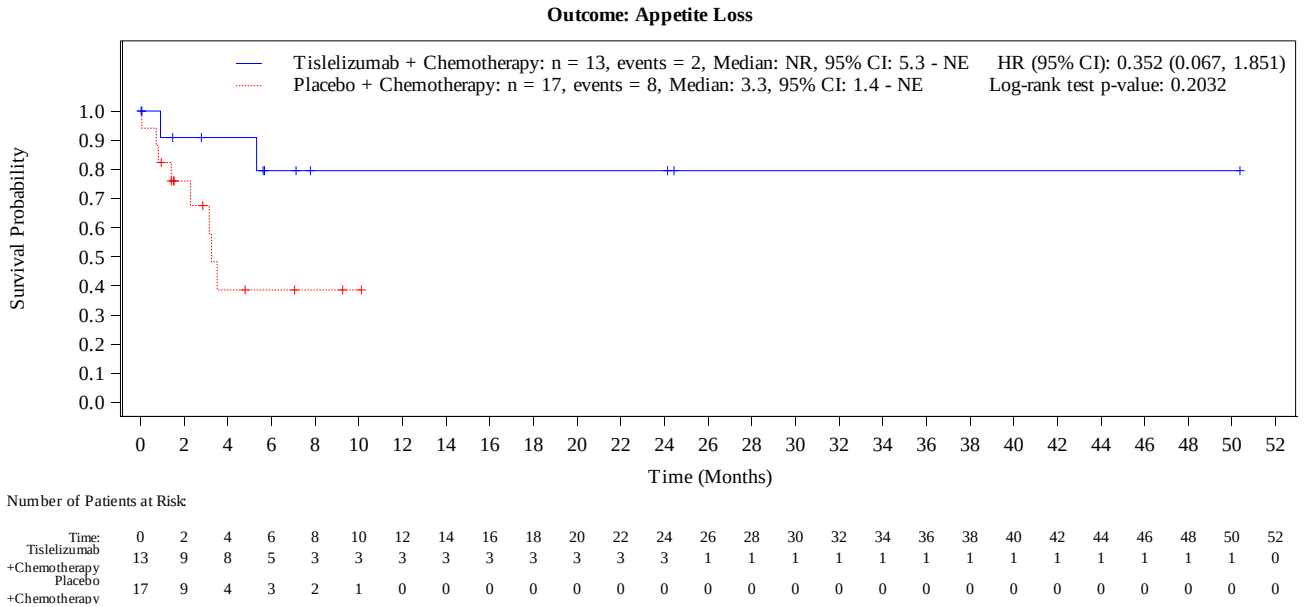
Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-3y.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-3y.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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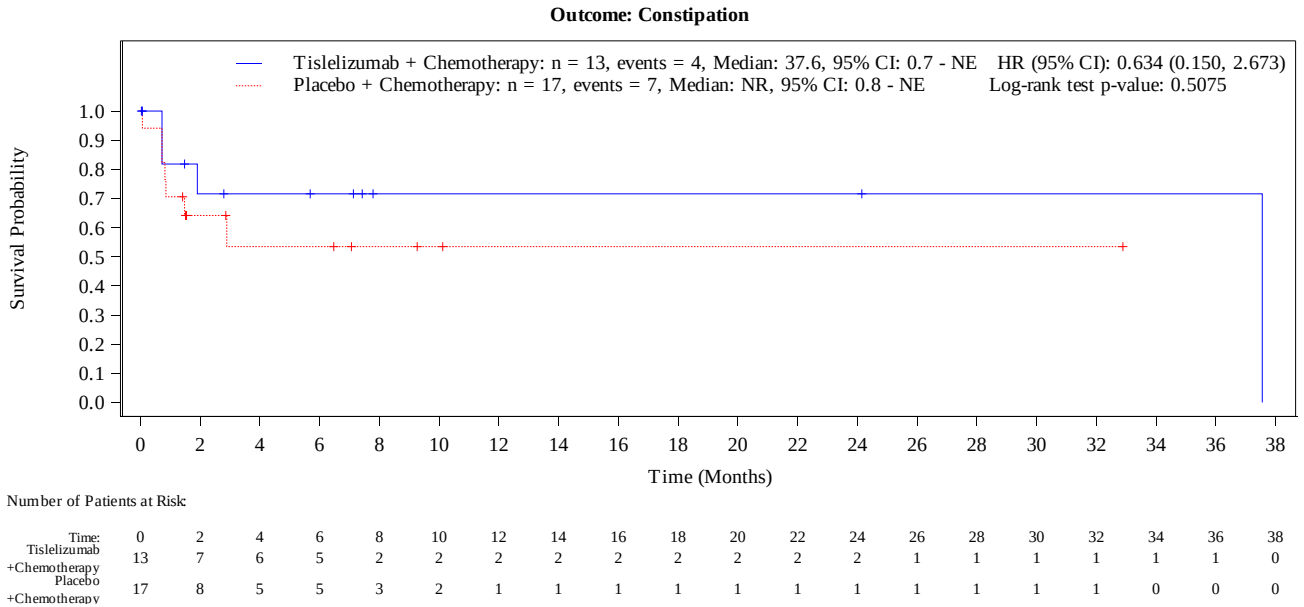
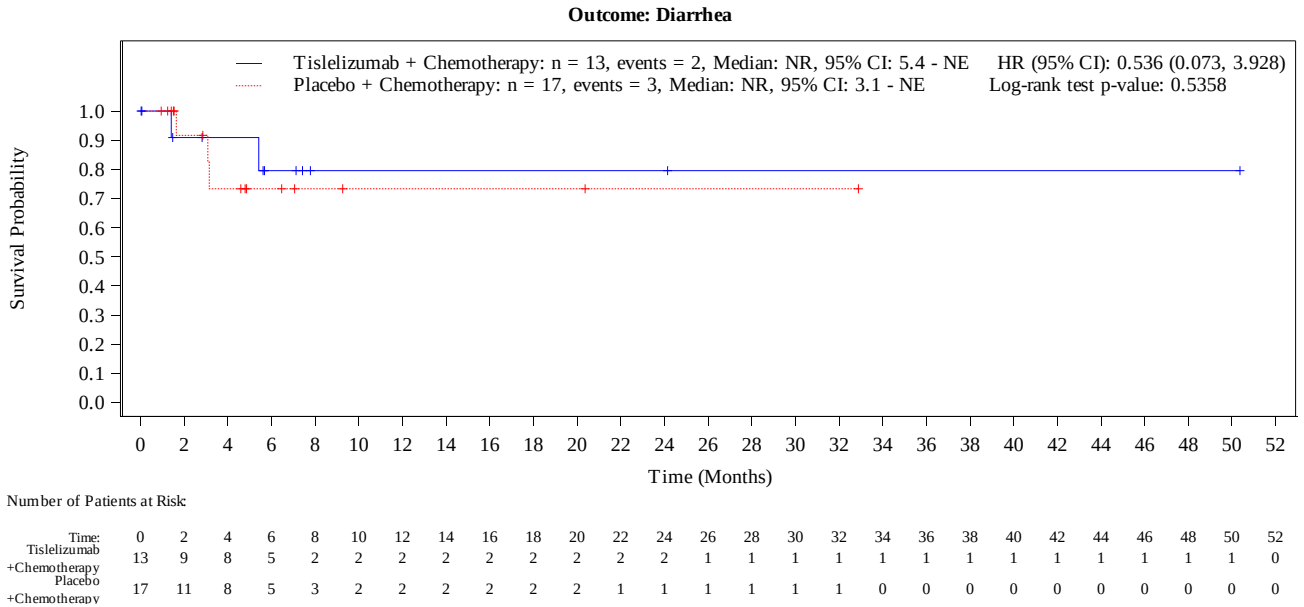
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-3y.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-3y.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-1-2-km-qs-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	6 (85.7)	--	--	--
No	9	0 (0.0)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	7 (63.6)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	3 (37.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	6 (75.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	7 (63.6)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	6 (60.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	7 (100.0)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	5 (83.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	2 (18.2)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	2 (33.3)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	3 (42.9)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

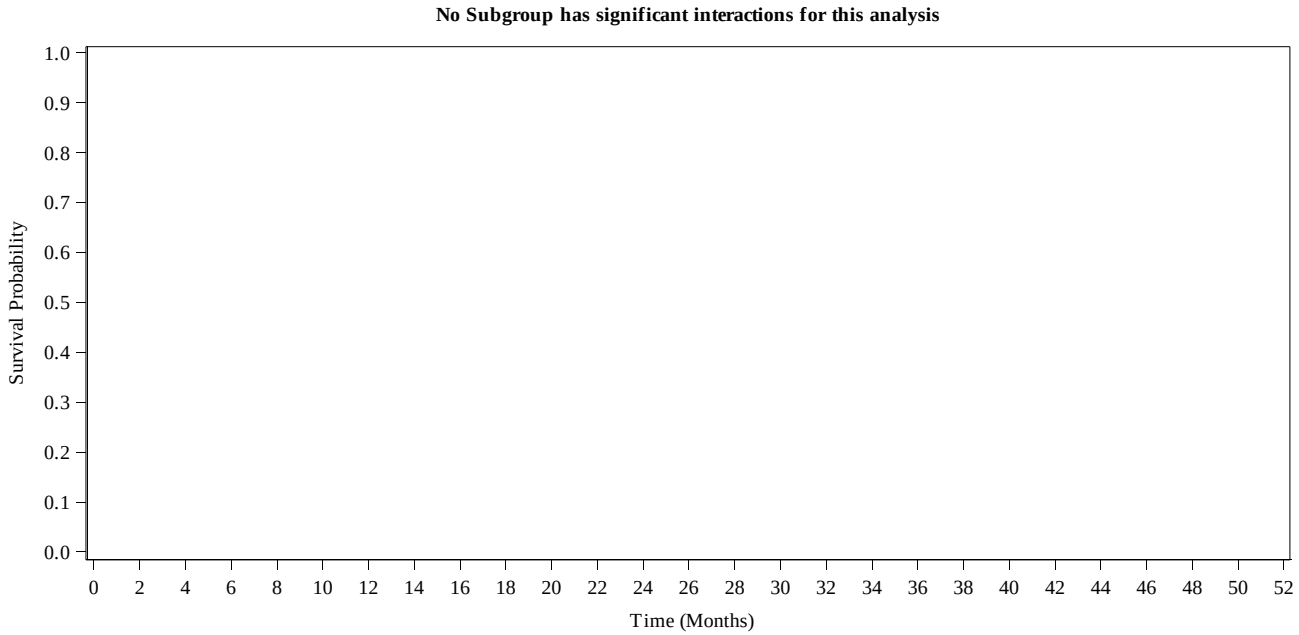
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-3y.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-1-2-s-km-tteqs-subgrp-c30-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	53.7 (36.03)		58.2 (33.22)	
	Median	61.1		66.7	
	Q1, Q3	22.2, 83.3		33.3, 77.8	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	63.3 (40.25)	4.4 (19.74)	60.0 (34.32)	0.0 (34.12)
	Median	77.8	5.6	66.7	0.0
	Q1, Q3	11.1, 100.0	0.0, 11.1	33.3, 88.9	-33.3, 11.1
	Min, Max	0, 100	-33, 44	0, 100	-56, 78
Cycle 3	n	10	10	11	11
	Mean (SD)	56.7 (36.83)	-2.2 (15.54)	44.4 (39.13)	-18.2 (22.92)
	Median	66.7	0.0	55.6	-11.1
	Q1, Q3	22.2, 88.9	0.0, 0.0	0.0, 88.9	-33.3, 0.0
	Min, Max	0, 100	-33, 22	0, 100	-56, 11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	75.3 (35.91)	19.8 (33.69)	37.0 (37.41)	-20.4 (23.61)
	Median	88.9	11.1	38.9	-11.1
	Q1, Q3	66.7, 100.0	0.0, 22.2	0.0, 66.7	-33.3, 0.0
	Min, Max	0, 100	-22, 89	0, 100	-67, 0
Cycle 5	n	8	8	11	11
	Mean (SD)	62.5 (40.69)	9.7 (22.57)	49.5 (38.61)	-13.1 (26.68)
	Median	83.3	11.1	44.4	-11.1
	Q1, Q3	22.2, 94.4	0.0, 22.2	11.1, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 44	0, 100	-67, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	66.7 (40.57)	14.3 (19.99)	54.3 (40.61)	-6.2 (31.48)
	Median	77.8	11.1	66.7	0.0
	Q1, Q3	22.2, 100.0	0.0, 22.2	11.1, 77.8	-11.1, 0.0
	Min, Max	0, 100	0, 56	0, 100	-67, 44

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	65.1 (46.00)	14.3 (46.13)	39.7 (41.00)	-15.9 (23.88)
	Median	88.9	0.0	33.3	-11.1
	Q1, Q3	0.0, 100.0	0.0, 55.6	0.0, 88.9	-22.2, 0.0
	Min, Max	0, 100	-56, 89	0, 100	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	47.2 (44.79)	-8.3 (33.18)	48.1 (45.36)	-7.4 (41.38)
	Median	44.4	0.0	44.4	0.0
	Q1, Q3	11.1, 83.3	-27.8, 11.1	0.0, 100.0	-44.4, 22.2
	Min, Max	0, 100	-56, 22	0, 100	-67, 44
Cycle 12	n	3	3	5	5
	Mean (SD)	7.4 (12.83)	-44.4 (61.86)	60.0 (43.46)	-6.7 (44.17)
	Median	0.0	-55.6	66.7	0.0
	Q1, Q3	0.0, 22.2	-100.0, 22.2	33.3, 100.0	-33.3, 22.2
	Min, Max	0, 22	-100, 22	0, 100	-67, 44

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	63.0 (54.81)	11.1 (98.76)	63.0 (54.81)	-25.9 (35.72)
	Median	88.9	44.4	88.9	-11.1
	Q1, Q3	0.0, 100.0	-100.0, 88.9	0.0, 100.0	-66.7, 0.0
	Min, Max	0, 100	-100, 89	0, 100	-67, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	37.0 (54.81)	-14.8 (75.63)	33.3 (47.14)	-22.2 (15.71)
	Median	11.1	11.1	33.3	-22.2
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-33.3, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-33, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	40.7 (44.91)	-11.1 (94.93)	22.2 (38.49)	-37.0 (27.96)
	Median	33.3	-22.2	0.0	-33.3
	Q1, Q3	0.0, 88.9	-100.0, 88.9	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 89	-100, 89	0, 67	-67, -11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	-18.5 (73.98)	22.2 (38.49)	-37.0 (27.96)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-67, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-40.7 (52.51)	40.7 (39.02)	-18.5 (50.10)
	Median	0.0	-22.2	44.4	-22.2
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 77.8	-66.7, 33.3
	Min, Max	0, 33	-100, 0	0, 78	-67, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-33.3 (94.28)	22.2 (38.49)	-37.0 (27.96)
	Median	16.7	-33.3	0.0	-33.3
	Q1, Q3	0.0, 33.3	-100.0, 33.3	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 33	-100, 33	0, 67	-67, -11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	29.6 (42.07)	-29.6 (23.13)
	Median	0.0	-50.0	11.1	-22.2
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 77.8	-55.6, -11.1
	Min, Max	0, 0	-100, 0	0, 78	-56, -11
Cycle 28	n	2	2	2	2
	Mean (SD)	5.6 (7.86)	-44.4 (78.57)	38.9 (55.00)	-16.7 (7.86)
	Median	5.6	-44.4	38.9	-16.7
	Q1, Q3	0.0, 11.1	-100.0, 11.1	0.0, 77.8	-22.2, -11.1
	Min, Max	0, 11	-100, 11	0, 78	-22, -11
Cycle 30	n	2	2	2	2
	Mean (SD)	5.6 (7.86)	-22.2 (47.14)	33.3 (47.14)	-22.2 (15.71)
	Median	5.6	-22.2	33.3	-22.2
	Q1, Q3	0.0, 11.1	-55.6, 11.1	0.0, 66.7	-33.3, -11.1
	Min, Max	0, 11	-56, 11	0, 67	-33, -11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	3.7 (6.42)	-48.1 (55.92)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-55.6	0.0	-11.1
	Q1, Q3	0.0, 11.1	-100.0, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-100, 11	0, 0	-11, -11
Cycle 34	n	3	3	1	1
	Mean (SD)	29.6 (51.32)	-22.2 (98.76)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-55.6	0.0	-11.1
	Q1, Q3	0.0, 88.9	-100.0, 88.9	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 89	-100, 89	0, 0	-11, -11
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-100.0 (NE)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-100.0	0.0	-11.1
	Q1, Q3	0.0, 0.0	-100.0, -100.0	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 0	-100, -100	0, 0	-11, -11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 42	n	1	1	1	1
	Mean (SD)	11.1 (NE)	-44.4 (NE)	22.2 (NE)	11.1 (NE)
	Median	11.1	-44.4	22.2	11.1
	Q1, Q3	11.1, 11.1	-44.4, -44.4	22.2, 22.2	11.1, 11.1
	Min, Max	11, 11	-44, -44	22, 22	11, 11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			22.2 (NE)	11.1 (NE)
	Median			22.2	11.1
	Q1, Q3			22.2, 22.2	11.1, 11.1
	Min, Max			22, 22	11, 11
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-55.6 (NE)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-55.6	0.0	-11.1
	Q1, Q3	0.0, 0.0	-55.6, -55.6	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 0	-56, -56	0, 0	-11, -11
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-55.6 (NE)		
	Median	0.0	-55.6		
	Q1, Q3	0.0, 0.0	-55.6, -55.6		
	Min, Max	0, 0	-56, -56		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	44.4 (NE)		
	Median	100.0	44.4		
	Q1, Q3	100.0, 100.0	44.4, 44.4		
	Min, Max	100, 100	44, 44		
Cycle 52	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-44.4 (NE)		
	Median	11.1	-44.4		
	Q1, Q3	11.1, 11.1	-44.4, -44.4		
	Min, Max	11, 11	-44, -44		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-55.6 (NE)		
	Median	0.0	-55.6		
	Q1, Q3	0.0, 0.0	-55.6, -55.6		
	Min, Max	0, 0	-56, -56		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-55.6 (NE)		
	Median	0.0	-55.6		
	Q1, Q3	0.0, 0.0	-55.6, -55.6		
	Min, Max	0, 0	-56, -56		
Cycle 64	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-33.3 (NE)		
	Median	22.2	-33.3		
	Q1, Q3	22.2, 22.2	-33.3, -33.3		
	Min, Max	22, 22	-33, -33		
End of Treatment	n	9	9	16	16
	Mean (SD)	53.1 (41.86)	4.9 (17.67)	52.1 (34.12)	-5.6 (34.43)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	0.0, 88.9	0.0, 0.0	22.2, 77.8	-27.8, 11.1
	Min, Max	0, 100	-11, 44	0, 100	-56, 78

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	75.9 (38.73)	22.2 (31.43)	82.4 (19.66)	24.2 (27.00)
	Median	94.4	16.7	88.9	22.2
	Q1, Q3	66.7, 100.0	0.0, 33.3	77.8, 100.0	11.1, 33.3
	Min, Max	0, 100	-11, 100	33, 100	-22, 78

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	27.1 (30.18)		29.4 (24.32)	
	Median	25.0		16.7	
	Q1, Q3	0.0, 33.3		8.3, 41.7	
	Min, Max	0, 100		0, 75	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.0 (17.92)	-10.8 (32.64)	35.6 (26.81)	6.1 (16.20)
	Median	8.3	0.0	33.3	0.0
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 41.7	-8.3, 16.7
	Min, Max	0, 50	-100, 17	0, 100	-17, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	15.0 (16.57)	-10.8 (31.93)	32.6 (26.99)	-0.8 (18.80)
	Median	12.5	0.0	25.0	0.0
	Q1, Q3	0.0, 25.0	0.0, 0.0	16.7, 50.0	-8.3, 16.7
	Min, Max	0, 42	-100, 8	0, 92	-42, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (12.11)	-15.7 (33.71)	34.7 (25.58)	4.2 (18.97)
	Median	8.3	0.0	25.0	0.0
	Q1, Q3	0.0, 8.3	-16.7, 0.0	16.7, 58.3	-4.2, 12.5
	Min, Max	0, 33	-100, 8	0, 75	-25, 50
Cycle 5	n	8	8	11	11
	Mean (SD)	10.4 (10.68)	-14.6 (32.35)	31.8 (29.06)	5.3 (26.42)
	Median	8.3	0.0	25.0	8.3
	Q1, Q3	0.0, 20.8	-16.7, 0.0	0.0, 66.7	-16.7, 25.0
	Min, Max	0, 25	-92, 8	0, 67	-42, 50
Cycle 6	n	7	7	9	9
	Mean (SD)	13.1 (16.57)	-1.2 (7.50)	25.9 (23.73)	0.0 (22.44)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	8.3, 33.3	-8.3, 16.7
	Min, Max	0, 33	-17, 8	0, 67	-42, 25

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	-17.9 (37.40)	21.4 (24.47)	3.6 (27.58)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 50.0	-16.7, 25.0
	Min, Max	0, 33	-100, 8	0, 58	-42, 42
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (15.96)	-18.8 (43.23)	19.4 (36.77)	0.0 (34.56)
	Median	25.0	0.0	0.0	-8.3
	Q1, Q3	8.3, 33.3	-41.7, 4.2	0.0, 25.0	-16.7, 16.7
	Min, Max	0, 33	-83, 8	0, 92	-42, 58
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-33.3 (57.74)	16.7 (28.26)	-6.7 (27.26)
	Median	0.0	0.0	8.3	-8.3
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 8.3	-16.7, 0.0
	Min, Max	0, 33	-100, 0	0, 67	-42, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	2.8 (4.81)	-41.7 (46.40)	16.7 (22.05)	-5.6 (12.73)
	Median	0.0	-33.3	8.3	-8.3
	Q1, Q3	0.0, 8.3	-91.7, 0.0	0.0, 41.7	-16.7, 8.3
	Min, Max	0, 8	-92, 0	0, 42	-17, 8
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-38.9 (41.94)	20.8 (29.46)	0.0 (11.79)
	Median	0.0	-33.3	20.8	0.0
	Q1, Q3	0.0, 16.7	-83.3, 0.0	0.0, 41.7	-8.3, 8.3
	Min, Max	0, 17	-83, 0	0, 42	-8, 8
Cycle 18	n	3	3	3	3
	Mean (SD)	19.4 (17.35)	-25.0 (43.30)	16.7 (16.67)	-2.8 (12.73)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-75.0, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-75, 0	0, 33	-17, 8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	16.7 (16.67)	-2.8 (12.73)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-67, 0	0, 33	-17, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	22.2 (19.25)	2.8 (20.97)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 25.0
	Min, Max	0, 33	-67, 0	0, 33	-17, 25
Cycle 24	n	2	2	3	3
	Mean (SD)	8.3 (11.79)	-8.3 (11.79)	19.4 (12.73)	0.0 (8.33)
	Median	8.3	-8.3	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	8.3, 33.3	-8.3, 8.3
	Min, Max	0, 17	-17, 0	8, 33	-8, 8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	12.5 (17.68)	-4.2 (5.89)	22.2 (9.62)	2.8 (4.81)
	Median	12.5	-4.2	16.7	0.0
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 33.3	0.0, 8.3
	Min, Max	0, 25	-8, 0	17, 33	0, 8
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	29.2 (5.89)	8.3 (11.79)
	Median	16.7	0.0	29.2	8.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	25.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 0	25, 33	0, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-50.0 (70.71)	20.8 (29.46)	0.0 (11.79)
	Median	16.7	-50.0	20.8	0.0
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 41.7	-8.3, 8.3
	Min, Max	0, 33	-100, 0	0, 42	-8, 8

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	19.4 (17.35)	-25.0 (43.30)	8.3 (NE)	0.0 (NE)
	Median	25.0	0.0	8.3	0.0
	Q1, Q3	0.0, 33.3	-75.0, 0.0	8.3, 8.3	0.0, 0.0
	Min, Max	0, 33	-75, 0	8, 8	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	8.3 (14.43)	-36.1 (37.58)	16.7 (NE)	8.3 (NE)
	Median	0.0	-33.3	16.7	8.3
	Q1, Q3	0.0, 25.0	-75.0, 0.0	16.7, 16.7	8.3, 8.3
	Min, Max	0, 25	-75, 0	17, 17	8, 8
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	8.3 (NE)	0.0 (NE)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	8.3, 8.3	0.0, 0.0
	Min, Max	0, 0	0, 0	8, 8	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			16.7 (NE)	8.3 (NE)
	Median			16.7	8.3
	Q1, Q3			16.7, 16.7	8.3, 8.3
	Min, Max			17, 17	8, 8
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	8.3 (NE)	0.0 (NE)
	Median	33.3	-66.7	8.3	0.0
	Q1, Q3	33.3, 33.3	-66.7, -66.7	8.3, 8.3	0.0, 0.0
	Min, Max	33, 33	-67, -67	8, 8	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	25.0 (NE)
	Median			33.3	25.0
	Q1, Q3			33.3, 33.3	25.0, 25.0
	Min, Max			33, 33	25, 25
Cycle 46	n	1	1	1	1
	Mean (SD)	41.7 (NE)	-58.3 (NE)	25.0 (NE)	16.7 (NE)
	Median	41.7	-58.3	25.0	16.7
	Q1, Q3	41.7, 41.7	-58.3, -58.3	25.0, 25.0	16.7, 16.7
	Min, Max	42, 42	-58, -58	25, 25	17, 17
Cycle 48	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	58.3 (NE)	-41.7 (NE)		
	Median	58.3	-41.7		
	Q1, Q3	58.3, 58.3	-41.7, -41.7		
	Min, Max	58, 58	-42, -42		
Cycle 52	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		
Cycle 56	n	1	1	0	0
	Mean (SD)	25.0 (NE)	-75.0 (NE)		
	Median	25.0	-75.0		
	Q1, Q3	25.0, 25.0	-75.0, -75.0		
	Min, Max	25, 25	-75, -75		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		
Cycle 64	n	1	1	0	0
	Mean (SD)	41.7 (NE)	-58.3 (NE)		
	Median	41.7	-58.3		
	Q1, Q3	41.7, 41.7	-58.3, -58.3		
	Min, Max	42, 42	-58, -58		
End of Treatment	n	9	9	16	16
	Mean (SD)	16.7 (15.59)	-0.9 (16.37)	39.6 (27.47)	9.4 (25.07)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 25.0	-8.3, 8.3	16.7, 58.3	0.0, 29.2
	Min, Max	0, 42	-33, 17	0, 83	-42, 58

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	36.1 (30.01)	9.0 (13.51)	56.4 (25.94)	27.0 (20.10)
	Median	33.3	8.3	50.0	25.0
	Q1, Q3	8.3, 58.3	0.0, 16.7	41.7, 66.7	16.7, 41.7
	Min, Max	0, 83	-17, 33	17, 100	-8, 58

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	4.2 (10.36)		12.7 (20.01)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 16.7	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (10.54)	14.4 (17.67)	3.3 (9.34)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 50	-17, 17
Cycle 3	n	10	10	11	11
	Mean (SD)	5.0 (11.25)	0.0 (7.86)	18.2 (17.41)	4.5 (16.82)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 17	0, 50	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	0.0 (0.00)	-5.6 (11.79)	13.9 (18.58)	1.4 (16.60)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 8.3
	Min, Max	0, 0	-33, 0	0, 50	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	2.1 (5.89)	-4.2 (7.72)	13.6 (17.98)	1.5 (17.41)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-8.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	0, 50	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	16.7 (16.67)	1.9 (22.74)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 50	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (0.00)	9.5 (16.27)	0.0 (21.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 33	0, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (20.97)	8.3 (9.62)	5.6 (13.61)	-5.6 (17.21)
	Median	16.7	8.3	0.0	0.0
	Q1, Q3	8.3, 33.3	0.0, 16.7	0.0, 0.0	-16.7, 0.0
	Min, Max	0, 50	0, 17	0, 33	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	6.7 (9.13)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	25.0 (11.79)	8.3 (11.79)
	Median	0.0	-16.7	25.0	8.3
	Q1, Q3	0.0, 16.7	-16.7, 0.0	16.7, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	17, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	22.2 (19.25)	11.1 (9.62)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 33	0, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	5.6 (9.62)	-5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	-16.7, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (9.62)	-5.6 (9.62)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 17	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (16.67)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 0	-33, 0	0, 33	-17, 17
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	16.7 (23.57)	0.0 (23.57)
	Median	0.0	-16.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 0	-33, 0	0, 33	-17, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	16.7 (23.57)	0.0 (23.57)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	16.7, 33.3	0.0, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	17, 33	0, 0	0, 33	-17, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	0.0 (NE)	-16.7 (NE)
	Median	16.7	0.0	0.0	-16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	0, 33	0, 0	0, 0	-17, -17
Cycle 34	n	3	3	1	1
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	16.7 (NE)	0.0 (NE)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	16.7, 16.7	0.0, 0.0
	Min, Max	0, 33	0, 0	17, 17	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	-16.7 (NE)
	Median	0.0	0.0	0.0	-16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	0, 0	0, 0	0, 0	-17, -17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 42	n	1	1	1	1
	Mean (SD)	16.7 (NE)	0.0 (NE)	33.3 (NE)	16.7 (NE)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	16.7, 16.7	0.0, 0.0	33.3, 33.3	16.7, 16.7
	Min, Max	17, 17	0, 0	33, 33	17, 17

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			16.7 (NE)	0.0 (NE)
	Median			16.7	0.0
	Q1, Q3			16.7, 16.7	0.0, 0.0
	Min, Max			17, 17	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	16.7 (NE)	0.0 (NE)	-16.7 (NE)
	Median	33.3	16.7	0.0	-16.7
	Q1, Q3	33.3, 33.3	16.7, 16.7	0.0, 0.0	-16.7, -16.7
	Min, Max	33, 33	17, 17	0, 0	-17, -17
Cycle 48	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-16.7 (NE)		
	Median	0.0	-16.7		
	Q1, Q3	0.0, 0.0	-16.7, -16.7		
	Min, Max	0, 0	-17, -17		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	66.7 (NE)	50.0 (NE)		
	Median	66.7	50.0		
	Q1, Q3	66.7, 66.7	50.0, 50.0		
	Min, Max	67, 67	50, 50		
Cycle 64	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
End of Treatment	n	9	9	16	16
	Mean (SD)	5.6 (8.33)	1.9 (15.47)	16.7 (16.10)	3.1 (19.45)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 33.3	-8.3, 16.7
	Min, Max	0, 17	-33, 17	0, 33	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	16.7 (22.47)	12.5 (16.09)	28.4 (18.41)	15.7 (16.11)
	Median	8.3	8.3	33.3	16.7
	Q1, Q3	0.0, 25.0	0.0, 16.7	16.7, 50.0	0.0, 33.3
	Min, Max	0, 67	0, 50	0, 50	-17, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	12.0 (18.02)		22.9 (20.21)	
	Median	0.0		22.2	
	Q1, Q3	0.0, 22.2		11.1, 33.3	
	Min, Max	0, 56		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.5 (21.61)	-1.5 (15.64)
	Median	0.0	0.0	22.2	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 22	-33, 11	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.2 (23.55)	-4.0 (15.13)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 0.0
	Min, Max	0, 22	-33, 11	0, 67	-33, 22

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (7.86)	-9.9 (15.16)	14.8 (18.55)	-8.3 (15.08)
	Median	0.0	0.0	5.6	-5.6
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 27.8	-16.7, 0.0
	Min, Max	0, 22	-33, 0	0, 56	-33, 11
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	-8.3 (12.94)	17.2 (25.99)	-3.0 (20.54)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 0	-33, 0	0, 89	-33, 44
Cycle 6	n	7	7	9	9
	Mean (SD)	1.6 (4.20)	-3.2 (10.57)	16.0 (21.60)	-2.5 (17.37)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-11.1, 0.0	0.0, 11.1	-11.1, 11.1
	Min, Max	0, 11	-22, 11	0, 67	-33, 22

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.74)	-4.8 (10.84)	7.9 (12.36)	-4.8 (14.14)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (10.64)	-5.6 (14.34)	7.4 (13.46)	-5.6 (15.32)
	Median	5.6	-5.6	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 5.6	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (11.11)	-7.4 (12.83)	6.7 (14.91)	-8.9 (14.49)
	Median	11.1	0.0	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, 0.0	0.0, 0.0	-11.1, 0.0
	Min, Max	0, 22	-22, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	14.8 (16.97)	0.0 (11.11)
	Median	0.0	-22.2	11.1	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 0	-33, 0	0, 33	-11, 11
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-22.2	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	3.7 (6.42)	-14.8 (12.83)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 11	-22, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	3.7 (27.96)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-22.2, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-22, 33	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	14.8 (16.97)	3.7 (6.42)
	Median	0.0	-11.1	11.1	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 11.1
	Min, Max	0, 0	-22, 0	0, 33	0, 11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-11.1	16.7	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	11.1 (0.00)	-16.7 (7.86)	16.7 (23.57)	0.0 (0.00)
	Median	11.1	-16.7	16.7	0.0
	Q1, Q3	11.1, 11.1	-22.2, -11.1	0.0, 33.3	0.0, 0.0
	Min, Max	11, 11	-22, -11	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	3.7 (6.42)	-14.8 (12.83)	0.0 (NE)	0.0 (NE)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 11	-22, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	7.4 (12.83)	-11.1 (11.11)	0.0 (NE)	0.0 (NE)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 22	-22, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	11.1 (NE)	11.1 (NE)
	Median	0.0	0.0	11.1	11.1
	Q1, Q3	0.0, 0.0	0.0, 0.0	11.1, 11.1	11.1, 11.1
	Min, Max	0, 0	0, 0	11, 11	11, 11

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 42	n	1	1	1	1
	Mean (SD)	22.2 (NE)	-11.1 (NE)	0.0 (NE)	0.0 (NE)
	Median	22.2	-11.1	0.0	0.0
	Q1, Q3	22.2, 22.2	-11.1, -11.1	0.0, 0.0	0.0, 0.0
	Min, Max	22, 22	-11, -11	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			11.1 (NE)	11.1 (NE)
	Median			11.1	11.1
	Q1, Q3			11.1, 11.1	11.1, 11.1
	Min, Max			11, 11	11, 11
Cycle 46	n	1	1	1	1
	Mean (SD)	11.1 (NE)	-22.2 (NE)	22.2 (NE)	22.2 (NE)
	Median	11.1	-22.2	22.2	22.2
	Q1, Q3	11.1, 11.1	-22.2, -22.2	22.2, 22.2	22.2, 22.2
	Min, Max	11, 11	-22, -22	22, 22	22, 22
Cycle 48	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-22.2 (NE)		
	Median	11.1	-22.2		
	Q1, Q3	11.1, 11.1	-22.2, -22.2		
	Min, Max	11, 11	-22, -22		
Cycle 52	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		
Cycle 56	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-22.2 (NE)		
	Median	11.1	-22.2		
	Q1, Q3	11.1, 11.1	-22.2, -22.2		
	Min, Max	11, 11	-22, -22		
End of Treatment	n	9	9	16	16
	Mean (SD)	6.2 (11.26)	-3.7 (21.52)	23.6 (22.91)	1.4 (19.82)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	5.6, 44.4	-11.1, 11.1
	Min, Max	0, 33	-44, 33	0, 67	-33, 44

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	20.4 (29.52)	8.3 (17.81)	35.9 (24.70)	13.1 (16.31)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	0.0, 27.8	11.1, 44.4	0.0, 22.2
	Min, Max	0, 89	-22, 33	0, 89	0, 44

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		17.6 (33.58)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	17.8 (24.77)	0.0 (41.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	-100, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	21.2 (37.34)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	25.0 (40.51)	2.8 (43.71)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 50.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	12.1 (22.47)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	-100, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (33.33)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 100	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.3 (37.80)	0.0 (57.74)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (57.74)	33.3 (57.74)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 100.0	0.0, 100.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	44.4 (50.92)	44.4 (50.92)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 0	0, 0	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	33.3 (57.74)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 100.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 100	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
End of Treatment	n	9	9	16	16
	Mean (SD)	14.8 (33.79)	14.8 (33.79)	41.7 (35.49)	25.0 (28.54)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	16.7, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	41.7 (37.94)	41.7 (37.94)	56.9 (36.83)	39.2 (35.81)
	Median	33.3	33.3	66.7	33.3
	Q1, Q3	16.7, 66.7	16.7, 66.7	33.3, 100.0	0.0, 66.7
	Min, Max	0, 100	0, 100	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		9.8 (15.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (30.63)	17.8 (17.21)	6.7 (18.69)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	0.0 (0.00)	-13.3 (23.31)	24.2 (33.63)	18.2 (34.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-67, 0	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-11.1 (28.87)	19.4 (30.01)	13.9 (30.01)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 100	0, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (17.25)	-4.2 (27.82)	15.2 (22.92)	9.1 (21.56)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	9.5 (16.27)	0.0 (0.00)	11.1 (16.67)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-14.3 (32.53)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (27.22)	11.1 (17.21)	5.6 (13.61)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 16.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	6.7 (14.91)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (0.00)	-11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 0	-67, 0	0, 0	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-66.7 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, -66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, -67	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-66.7 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, -66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, -67	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
End of Treatment	n	9	9	16	16
	Mean (SD)	7.4 (14.70)	0.0 (23.57)	27.1 (27.81)	16.7 (29.81)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	19.4 (17.16)	5.6 (23.92)	35.3 (24.92)	25.5 (30.11)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		15.7 (29.15)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	6.7 (21.08)	31.1 (29.46)	13.3 (24.56)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	20.0 (17.21)	3.3 (24.60)	27.3 (29.13)	12.1 (16.82)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	25.9 (22.22)	7.4 (14.70)	30.6 (30.01)	16.7 (22.47)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	16.7 (25.20)	0.0 (17.82)	24.2 (26.21)	18.2 (22.92)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	19.0 (26.23)	9.5 (25.20)	25.9 (22.22)	18.5 (17.57)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (17.82)	0.0 (19.25)	9.5 (16.27)	4.8 (12.60)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (47.14)	16.7 (27.89)	11.1 (17.21)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-67, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	0.0 (33.33)	20.0 (18.26)	13.3 (18.26)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	50.0 (23.57)	33.3 (0.00)
	Median	0.0	0.0	50.0	33.3
	Q1, Q3	0.0, 33.3	-66.7, 0.0	33.3, 66.7	33.3, 33.3
	Min, Max	0, 33	-67, 0	33, 67	33, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	33.3 (33.33)	22.2 (38.49)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-67, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	44.4 (50.92)	33.3 (57.74)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	0.0 (0.00)	33.3 (33.33)	22.2 (38.49)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 67	0, 0	0, 67	0, 67
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (47.14)	22.2 (19.25)	11.1 (19.25)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	33.3 (33.33)	22.2 (38.49)
	Median	0.0	-16.7	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-33, 0	0, 67	0, 67
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	50.0 (23.57)	33.3 (47.14)
	Median	0.0	-16.7	50.0	33.3
	Q1, Q3	0.0, 0.0	-33.3, 0.0	33.3, 66.7	0.0, 66.7
	Min, Max	0, 0	-33, 0	33, 67	0, 67
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-33.3 (0.00)	33.3 (0.00)	16.7 (23.57)
	Median	16.7	-33.3	33.3	16.7
	Q1, Q3	0.0, 33.3	-33.3, -33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, -33	33, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 66.7	-33.3, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 67	-33, 0	33, 33	33, 33
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-22.2 (19.25)	66.7 (NE)	66.7 (NE)
	Median	0.0	-33.3	66.7	66.7
	Q1, Q3	0.0, 33.3	-33.3, 0.0	66.7, 66.7	66.7, 66.7
	Min, Max	0, 33	-33, 0	67, 67	67, 67
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	0.0	33.3	33.3
	Q1, Q3	66.7, 66.7	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	0, 0	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	0.0	33.3	33.3
	Q1, Q3	66.7, 66.7	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	66.7 (NE)	0.0 (NE)		
	Median	66.7	0.0		
	Q1, Q3	66.7, 66.7	0.0, 0.0		
	Min, Max	67, 67	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
End of Treatment	n	9	9	16	16
	Mean (SD)	14.8 (17.57)	3.7 (30.93)	35.4 (35.42)	18.8 (32.13)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 50.0
	Min, Max	0, 33	-33, 33	0, 100	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	47.2 (22.29)	25.0 (20.72)	49.0 (33.58)	33.3 (31.18)
	Median	33.3	33.3	33.3	33.3
	Q1, Q3	33.3, 66.7	33.3, 33.3	33.3, 66.7	0.0, 66.7
	Min, Max	33, 100	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	11.1 (29.59)		9.8 (19.60)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 0.0	
	Min, Max	0, 100		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	24.4 (29.46)	13.3 (24.56)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	27.3 (35.96)	15.2 (37.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (26.06)	30.6 (36.12)	19.4 (26.43)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 100	0, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (24.80)	0.0 (17.82)	27.3 (29.13)	21.2 (30.81)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	37.0 (35.14)	33.3 (33.33)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (25.20)	23.8 (37.09)	19.0 (37.80)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (27.22)	16.7 (40.82)	11.1 (27.22)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (19.25)	-11.1 (50.92)	20.0 (29.81)	13.3 (18.26)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-50.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	-33.3	33.3	33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	-33, -33	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	100.0	0.0	0.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	100, 100	0, 0	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
End of Treatment	n	9	9	16	16
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	27.1 (34.89)	18.8 (29.74)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	16.7 (30.15)	5.6 (19.25)	51.0 (37.49)	41.2 (32.34)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 16.7	33.3, 100.0	33.3, 66.7
	Min, Max	0, 100	-33, 33	0, 100	0, 100

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	2.8 (9.62)		13.7 (23.74)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	13.3 (21.08)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	15.2 (22.92)	0.0 (25.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	7.4 (14.70)	19.4 (26.43)	5.6 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	4.2 (11.79)	15.2 (22.92)	6.1 (25.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	11.1 (23.57)	0.0 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	16.7 (40.82)	11.1 (27.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	33.3	33.3	33.3
	Q1, Q3	33.3, 33.3	33.3, 33.3	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	33, 33	33, 33	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
End of Treatment	n	9	9	16	16
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	27.1 (27.81)	12.5 (26.87)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 50.0	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	13.9 (17.16)	11.1 (21.71)	39.2 (33.82)	25.5 (27.71)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	8.3 (15.08)		15.7 (23.91)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 16.7		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (14.05)	20.0 (27.60)	4.4 (27.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	-3.3 (10.54)	18.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-7.4 (14.70)	19.4 (30.01)	2.8 (22.29)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 100	-33, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-8.3 (15.43)	21.2 (26.97)	6.1 (32.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	-4.8 (12.60)	11.1 (16.67)	-7.4 (22.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (16.27)	9.5 (16.27)	-9.5 (25.20)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (0.00)	11.1 (27.22)	-11.1 (34.43)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	6.7 (14.91)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	16.7 (23.57)	-16.7 (23.57)
	Median	0.0	-33.3	16.7	-16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	11.1 (19.25)	-11.1 (19.25)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 33	-33, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	16.7 (23.57)	-16.7 (23.57)
	Median	16.7	0.0	16.7	-16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 33	-33, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (0.00)	16.7 (23.57)	-16.7 (23.57)
	Median	0.0	-33.3	16.7	-16.7
	Q1, Q3	0.0, 0.0	-33.3, -33.3	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, -33	0, 33	-33, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (NE)	-33.3 (NE)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (NE)	-33.3 (NE)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	0.0 (NE)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	33, 33	0, 0

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-33.3 (NE)
	Median			0.0	-33.3
	Q1, Q3			0.0, 0.0	-33.3, -33.3
	Min, Max			0, 0	-33, -33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	0.0 (NE)	66.7 (NE)	33.3 (NE)
	Median	33.3	0.0	66.7	33.3
	Q1, Q3	33.3, 33.3	0.0, 0.0	66.7, 66.7	33.3, 33.3
	Min, Max	33, 33	0, 0	67, 67	33, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-33.3 (NE)	33.3 (NE)	0.0 (NE)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, -33.3	33.3, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, -33	33, 33	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
End of Treatment	n	9	9	16	16
	Mean (SD)	0.0 (0.00)	-7.4 (14.70)	18.8 (24.25)	2.1 (25.73)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 67	-67, 33

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	5.6 (12.97)	-2.8 (9.62)	39.2 (35.81)	23.5 (28.30)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 100	-33, 67

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-3-1-qs-chg-oes-pop1-3y.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	53.70 (36.03)	-8.93 (6.75)	17	58.17 (33.22)	-12.75 (5.13)	3.82 (-11.92, 19.56)	0.21 (-0.64, 1.06)	0.6191

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-3y.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Eating									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	27.08 (30.18)	-11.10 (6.84)	17	29.41 (24.32)	3.42 (5.04)	-14.52 (-30.47, 1.44)	-0.75 (-1.59, 0.09)	0.0723

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-3y.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Reflux									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	4.17 (10.36)	-3.87 (2.35)	17	12.75 (20.01)	4.72 (1.91)	-8.58 (-14.10, -3.06)	-1.52 (-2.56, -0.48)	0.0036

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-3y.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain (OES18)									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	12.04 (18.02)	-8.04 (3.89)	17	22.88 (20.21)	-0.52 (3.02)	-7.52 (-16.84, 1.80)	-0.73 (-1.63, 0.18)	0.1083

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-3y.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble swallowing saliva									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	-1.67 (6.34)	17	17.65 (33.58)	5.04 (5.07)	-6.71 (-21.97, 8.55)	-0.39 (-1.27, 0.49)	0.3700

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-3y.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Choked when swallowing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-8.65 (5.46)	17	9.80 (15.66)	9.96 (4.07)	-18.61 (-31.24, -5.97)	-1.30 (-2.25, -0.35)	0.0060

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dry mouth									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	7.19 (5.42)	17	15.69 (29.15)	13.10 (4.12)	-5.91 (-18.43, 6.62)	-0.42 (-1.31, 0.46)	0.3397

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with taste									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	11.11 (29.59)	-12.08 (7.60)	17	9.80 (19.60)	9.77 (5.46)	-21.84 (-38.98, -4.70)	-1.08 (-1.97, -0.19)	0.0149

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-3y.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with coughing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	2.78 (9.62)	-0.18 (5.25)	17	13.73 (23.74)	4.28 (3.89)	-4.46 (-17.06, 8.14)	-0.32 (-1.20, 0.57)	0.4723

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

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[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble talking									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	8.33 (15.08)	-3.39 (5.29)	17	15.69 (23.91)	7.76 (3.93)	-11.15 (-23.89, 1.59)	-0.76 (-1.64, 0.12)	0.0818

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-3y.rtf

Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	13	7 (53.8)	2.9 (0.1, NE)	17	5 (29.4)	NR (6.4, NE)	3.765 (0.748, 18.944)	0.0754
Eating	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	NR (0.8, NE)	0.269 (0.030, 2.390)	0.2122
Reflux	13	2 (15.4)	NR (1.9, NE)	17	6 (35.3)	NR (1.4, NE)	0.499 (0.090, 2.772)	0.4197
Pain	13	1 (7.7)	NR (NE, NE)	17	5 (29.4)	24.4 (0.8, NE)	0.648 (0.055, 7.567)	0.7273
Trouble Swallowing Saliva	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	29.9 (1.0, NE)	0.242 (0.026, 2.297)	0.1857
Choked When Swallowing	13	1 (7.7)	NR (2.3, NE)	17	5 (29.4)	NR (1.5, NE)	0.324 (0.035, 3.050)	0.3032

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-3-1-2-eff-tte-qlq-oes-pop1-3y.rtf

Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dry Mouth	13	3 (23.1)	NR (2.3, NE)	17	9 (52.9)	2.2 (0.7, NE)	0.393 (0.095, 1.630)	0.1859
Trouble With Taste	13	2 (15.4)	NR (2.8, NE)	17	8 (47.1)	3.3 (0.8, NE)	0.279 (0.056, 1.384)	0.0975
Trouble With Coughing	13	3 (23.1)	26.0 (0.7, NE)	17	4 (23.5)	NR (2.2, NE)	0.648 (0.103, 4.061)	0.6402
Trouble Talking	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (3.2, NE)	0.000 (0.000, NE)	0.2489

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

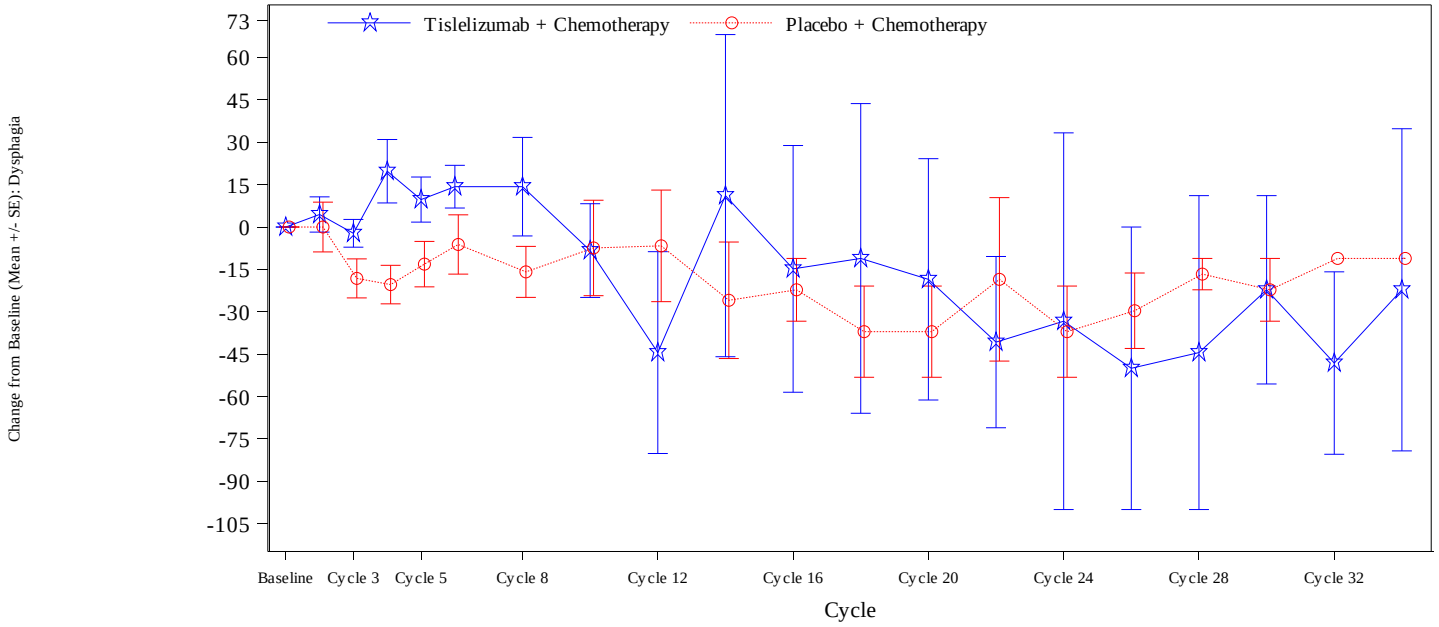
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-3-1-2-eff-tte-qlq-oes-pop1-3y.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

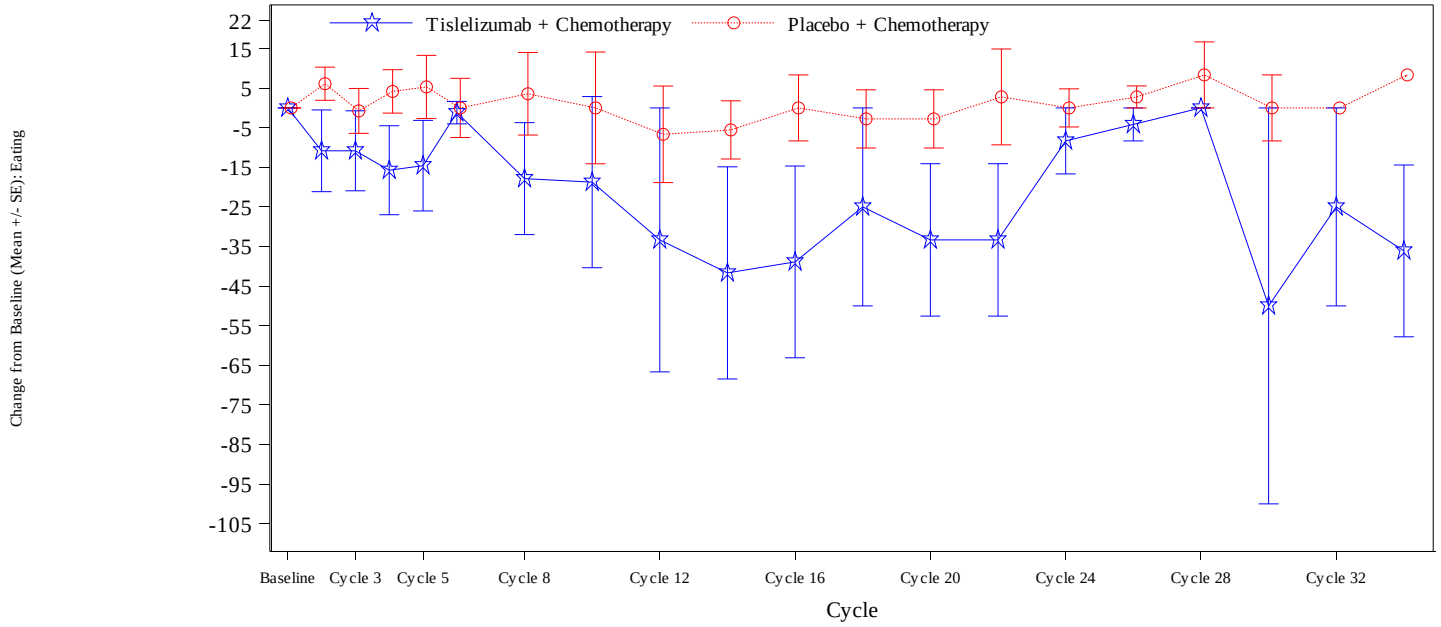


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-2-series-o18-pop1-3y.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

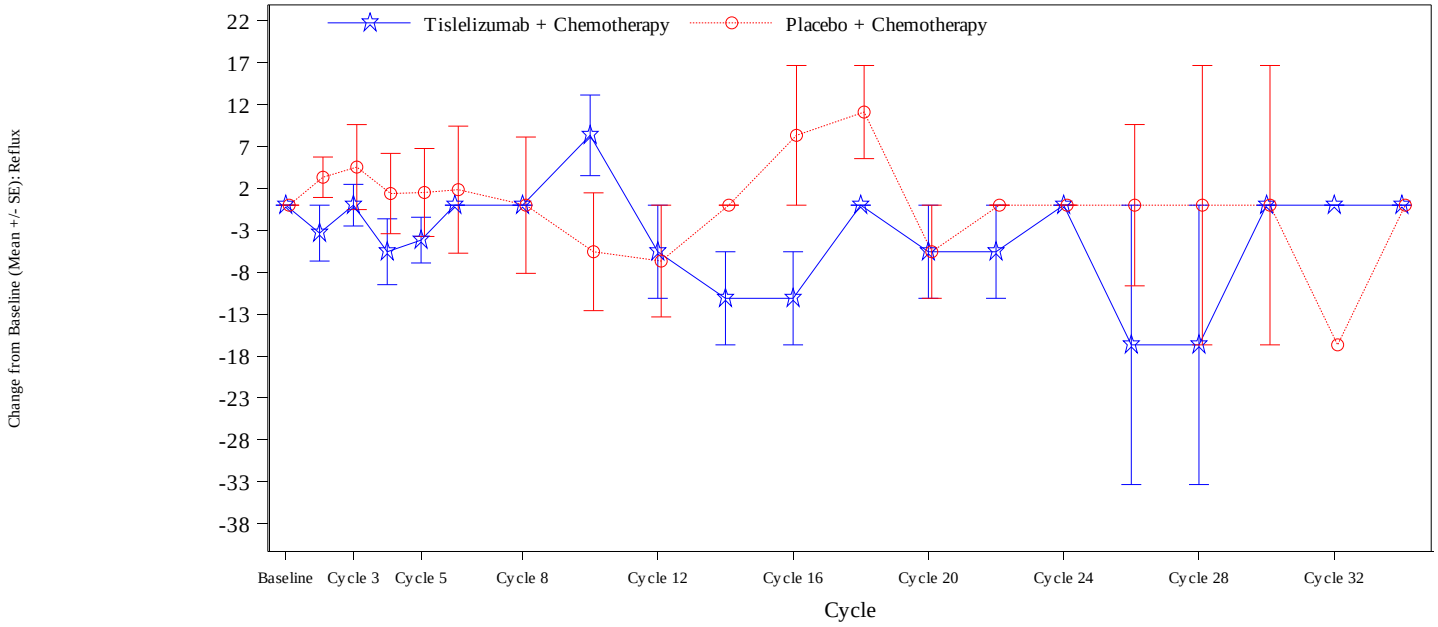


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-2-series-o18-pop1-3y.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

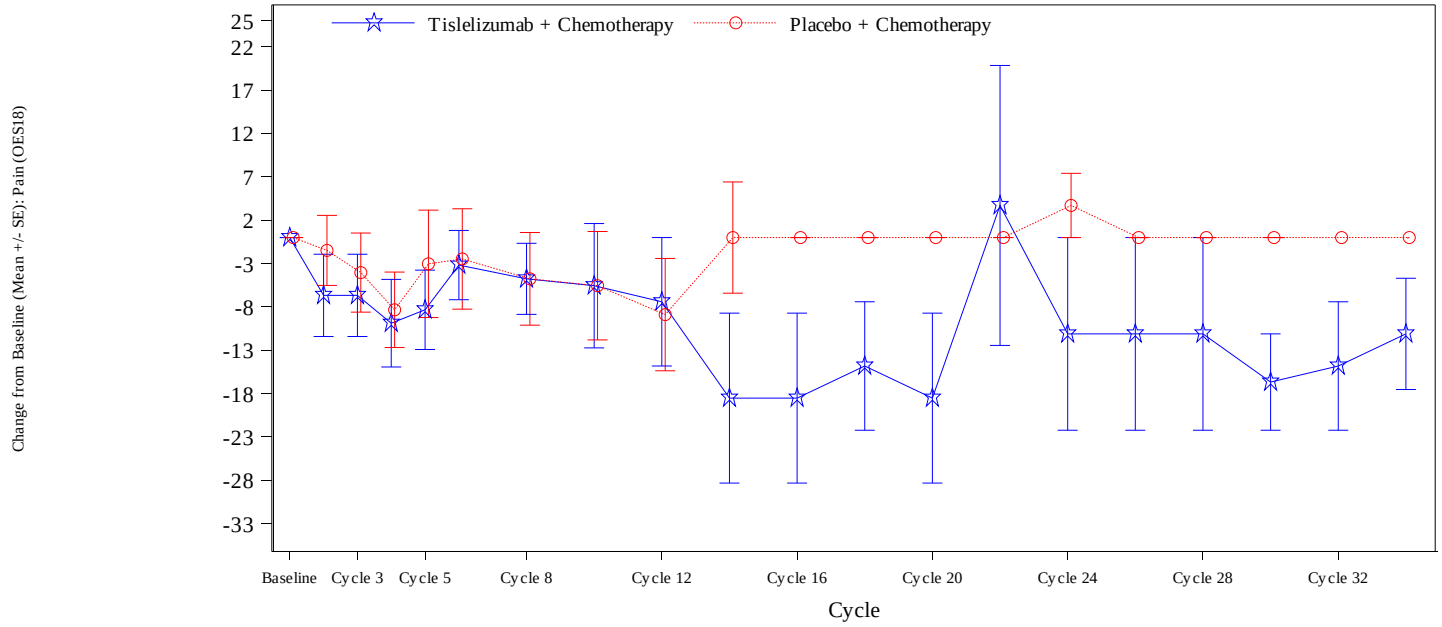


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-2-series-o18-pop1-3y.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
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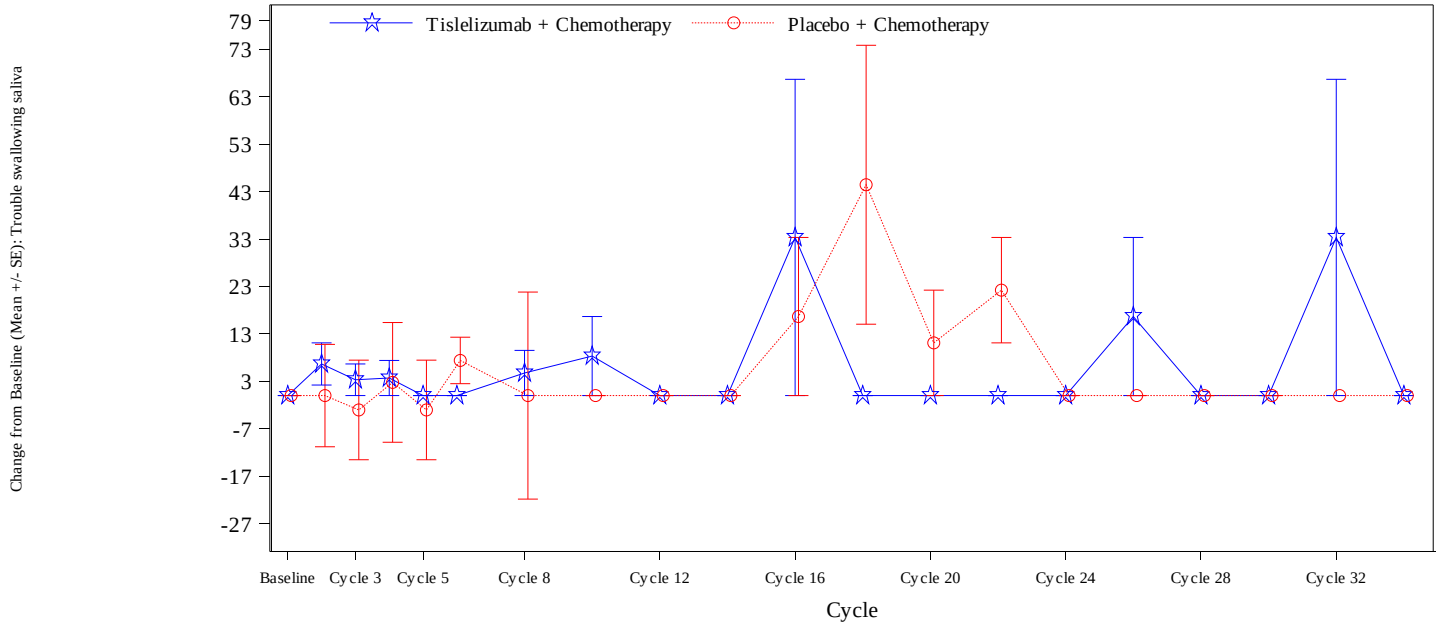

No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
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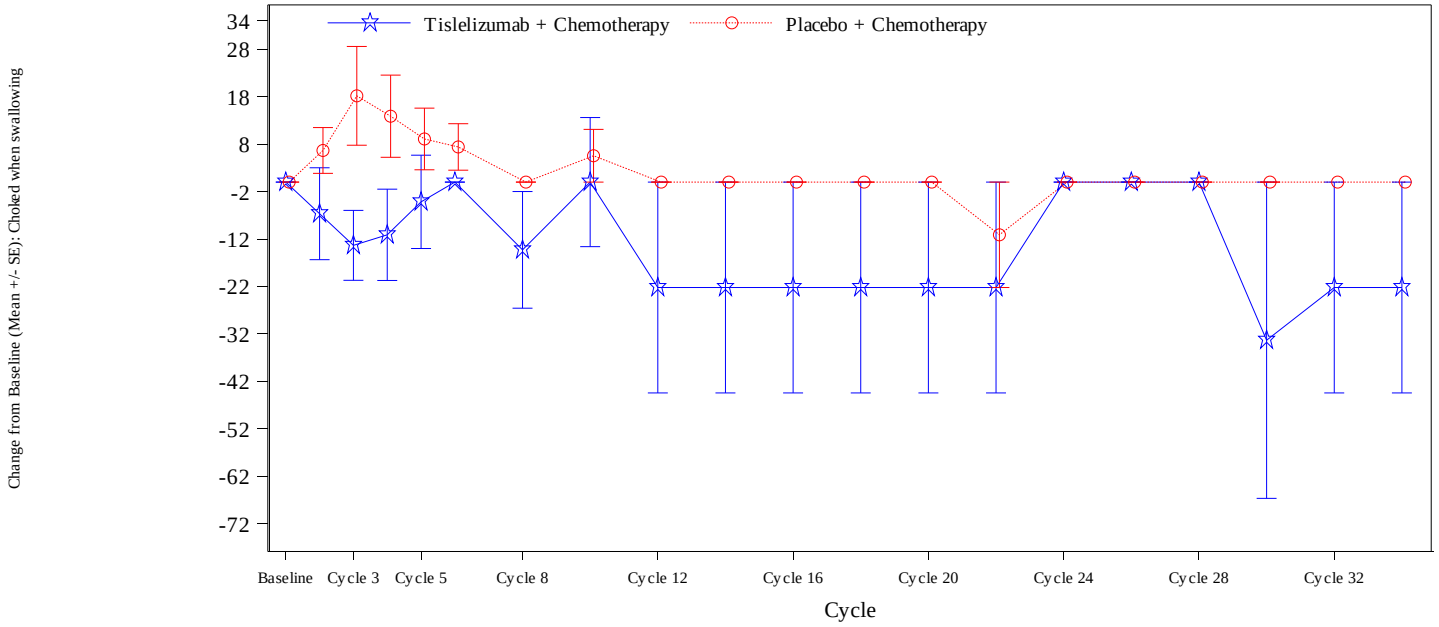

No. of Patients

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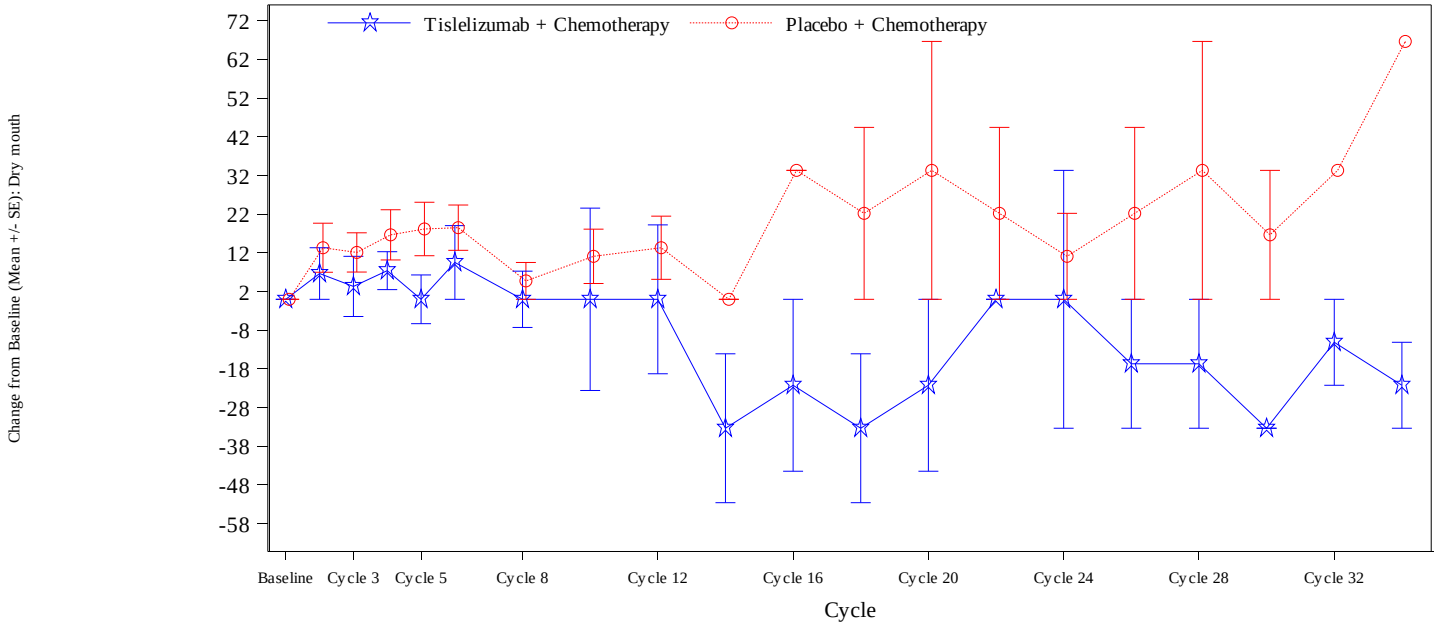

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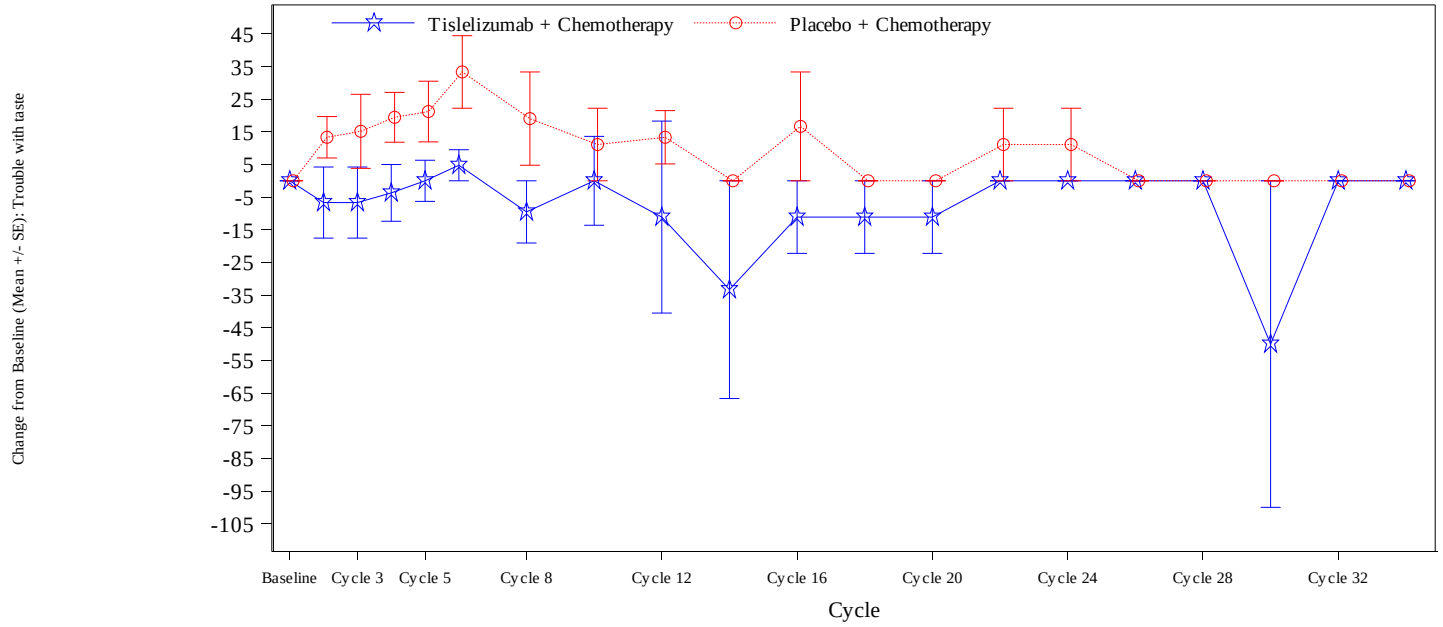

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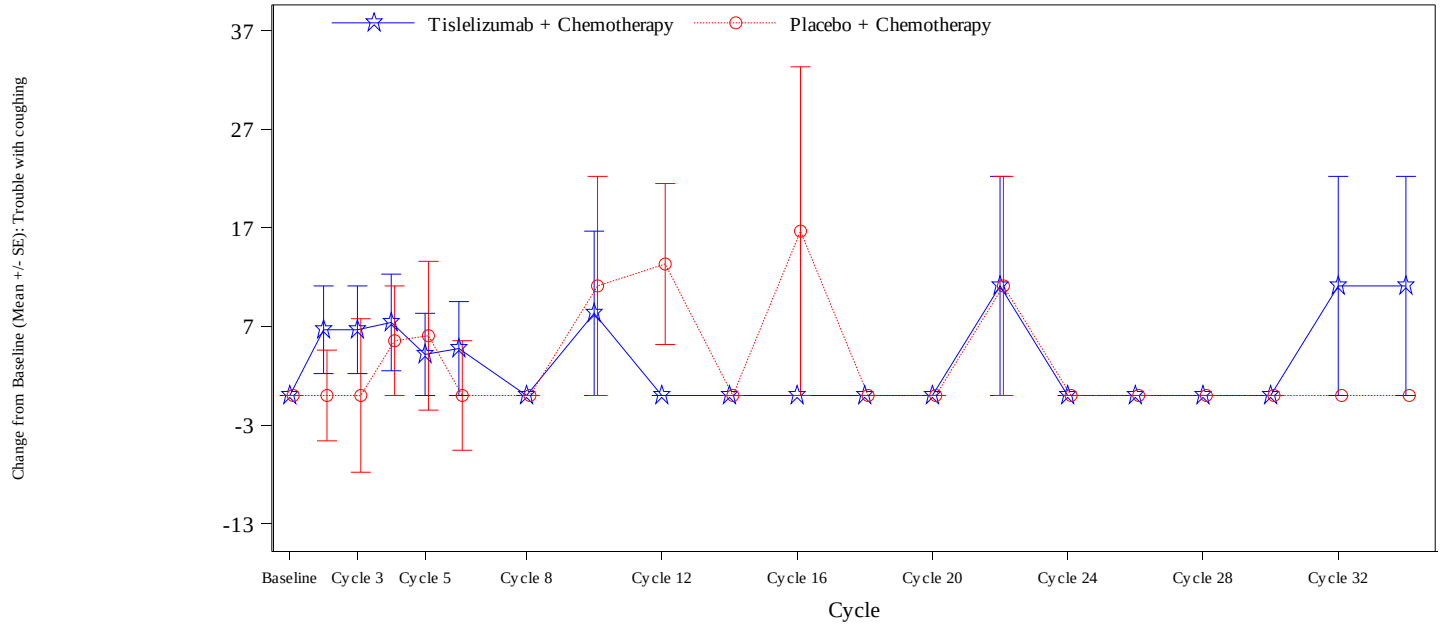

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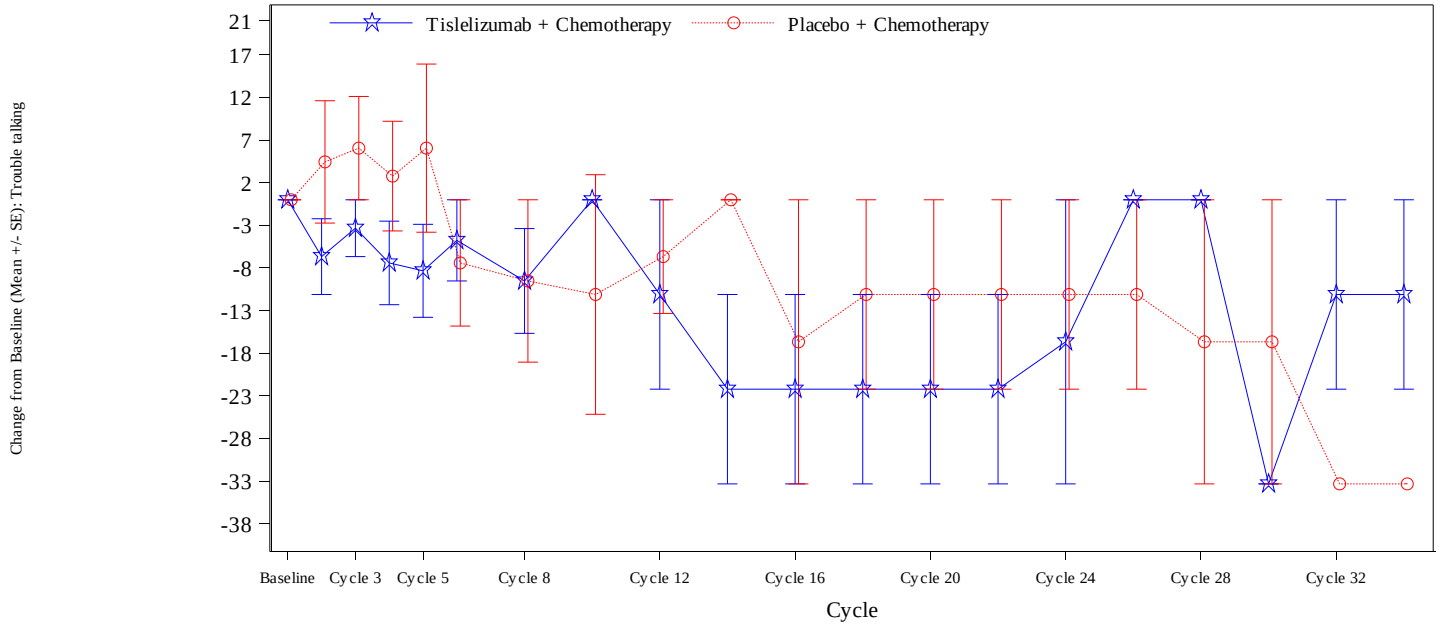

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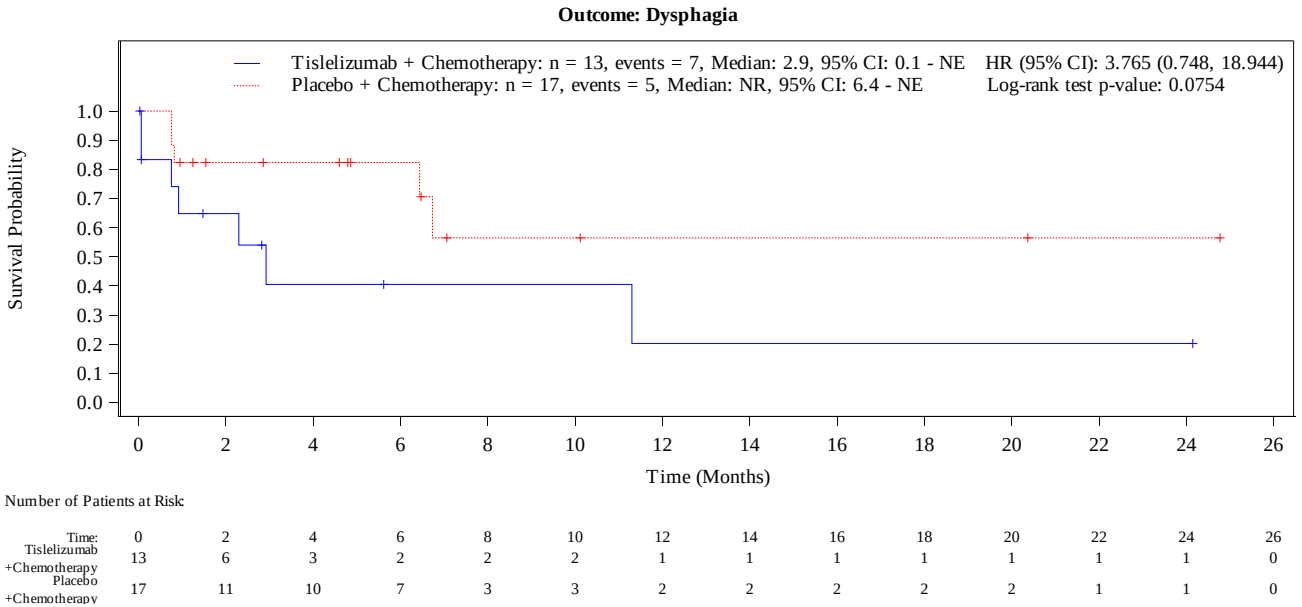
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
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unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-3y.rtf

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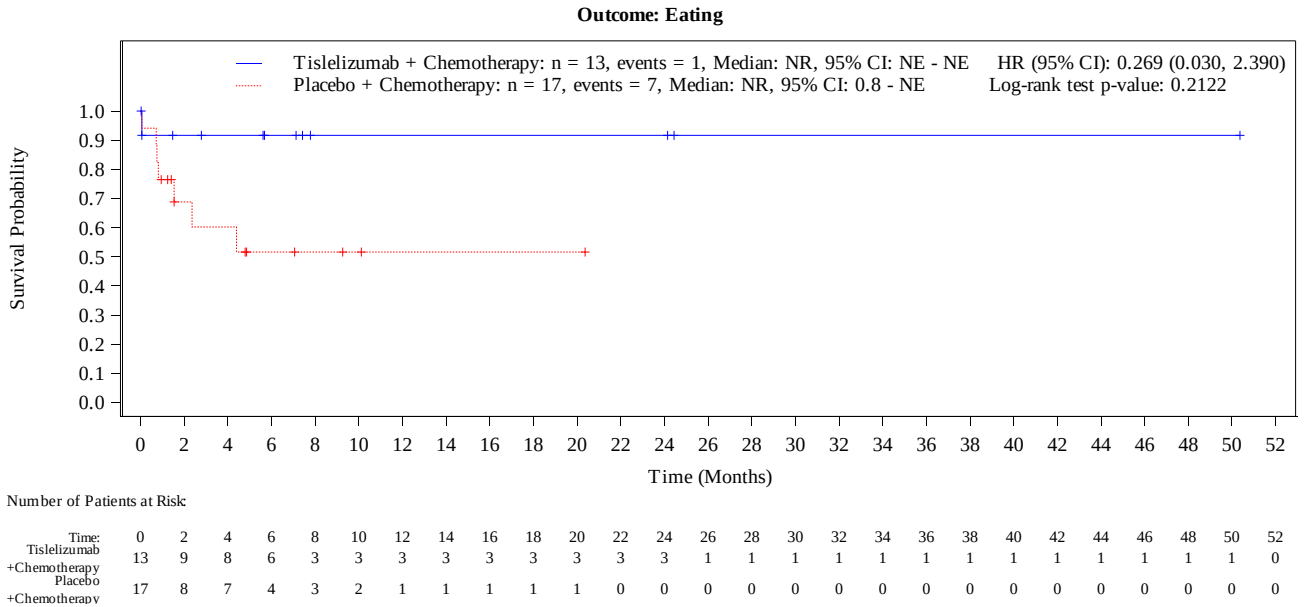
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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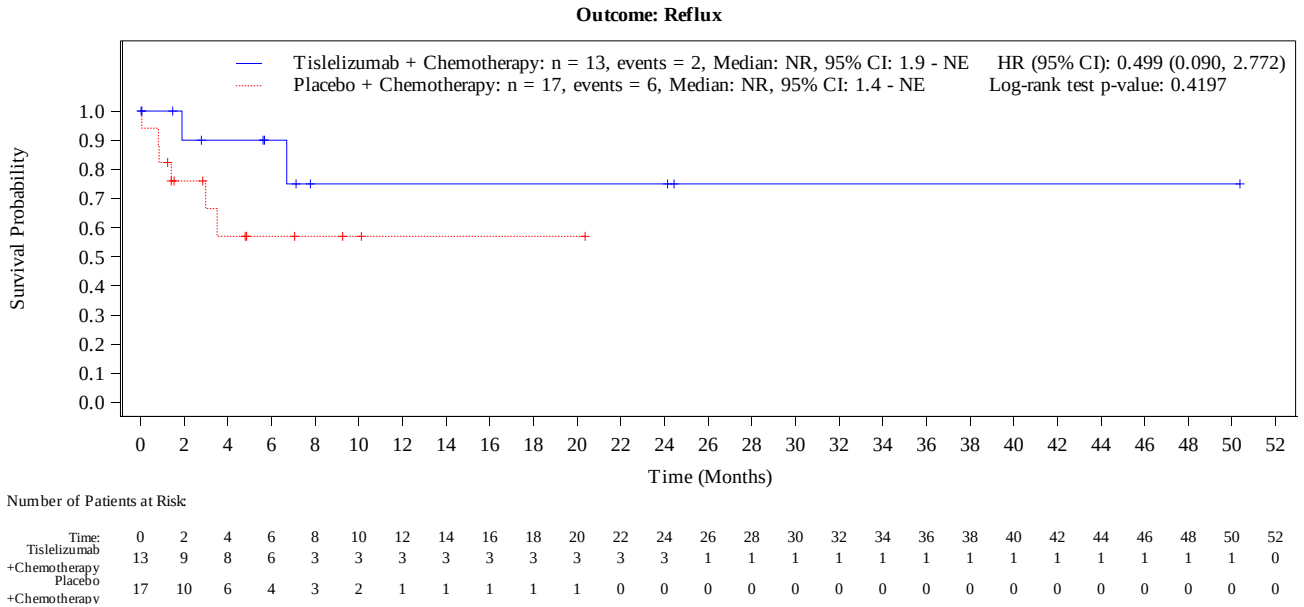

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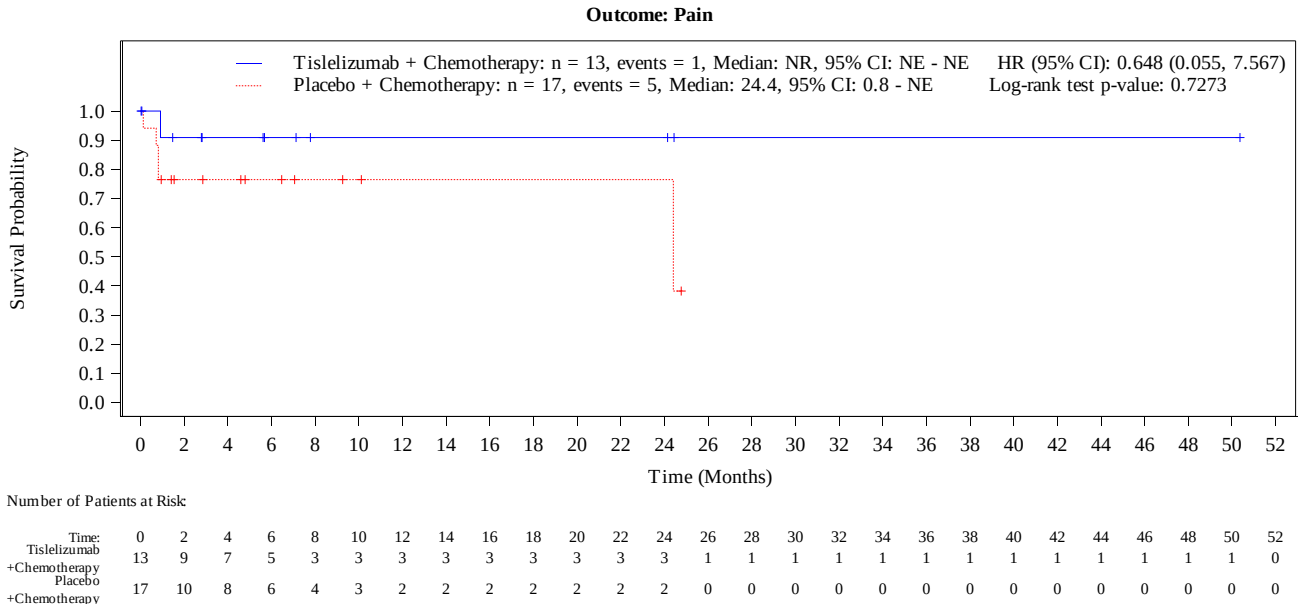

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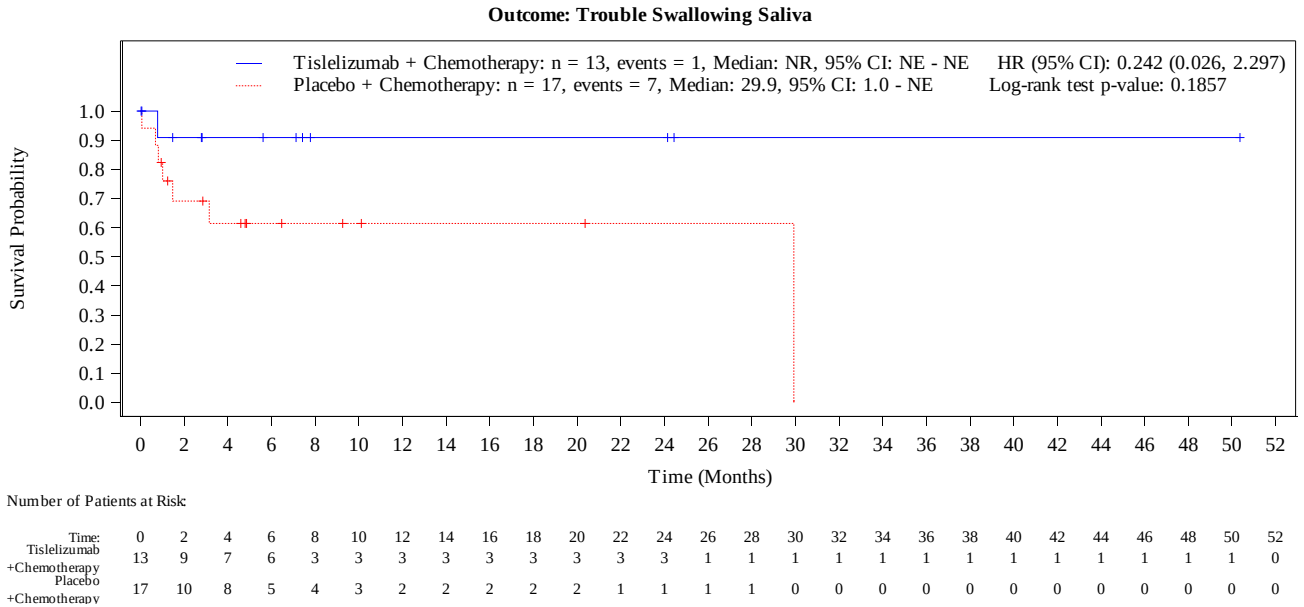

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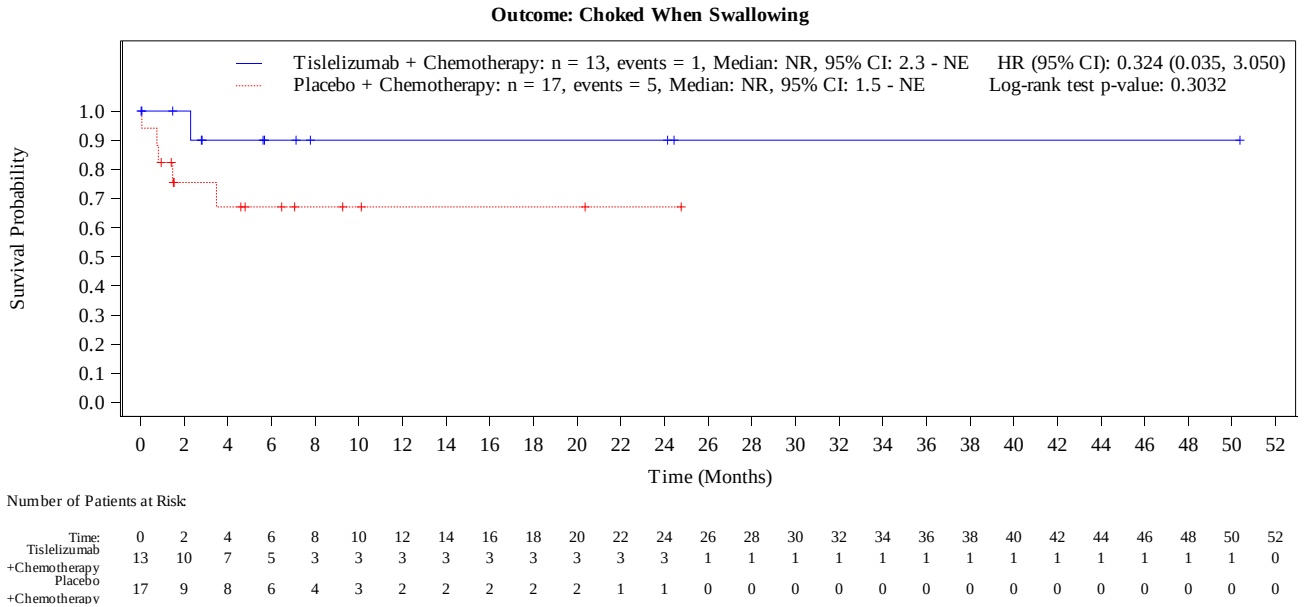

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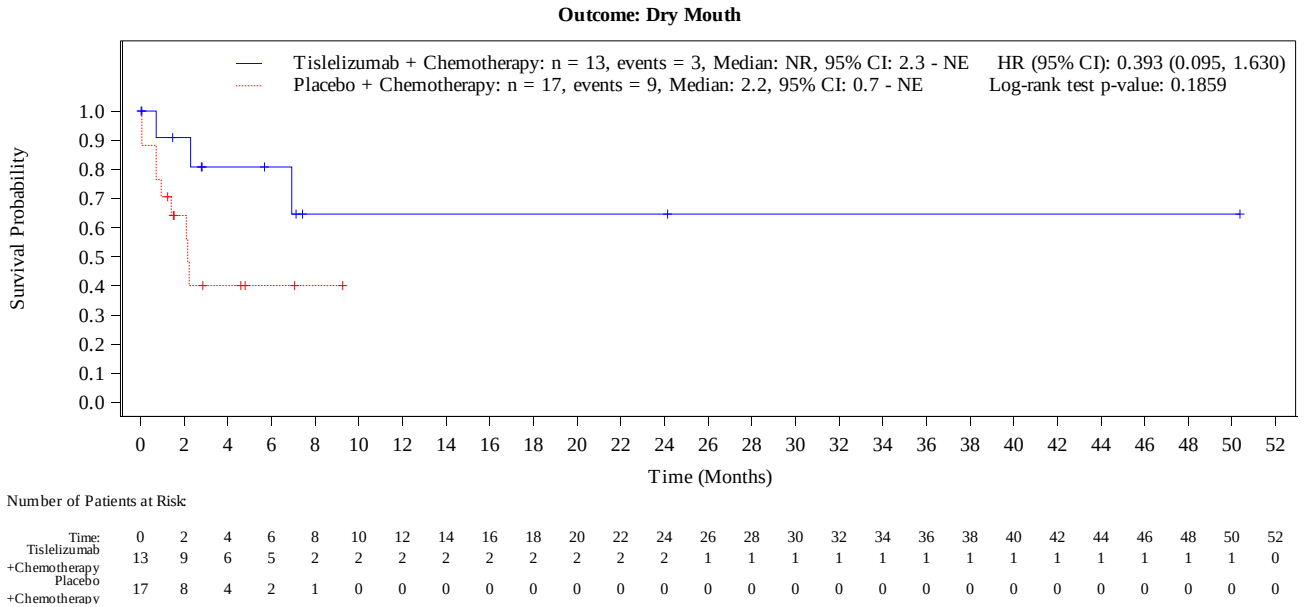

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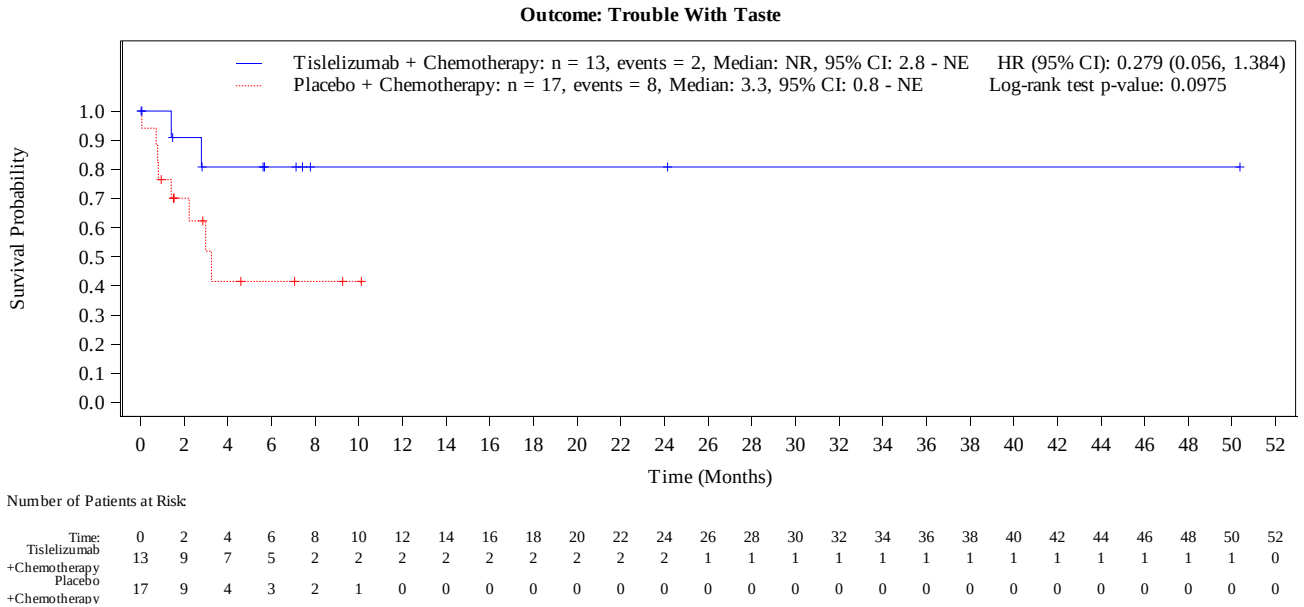

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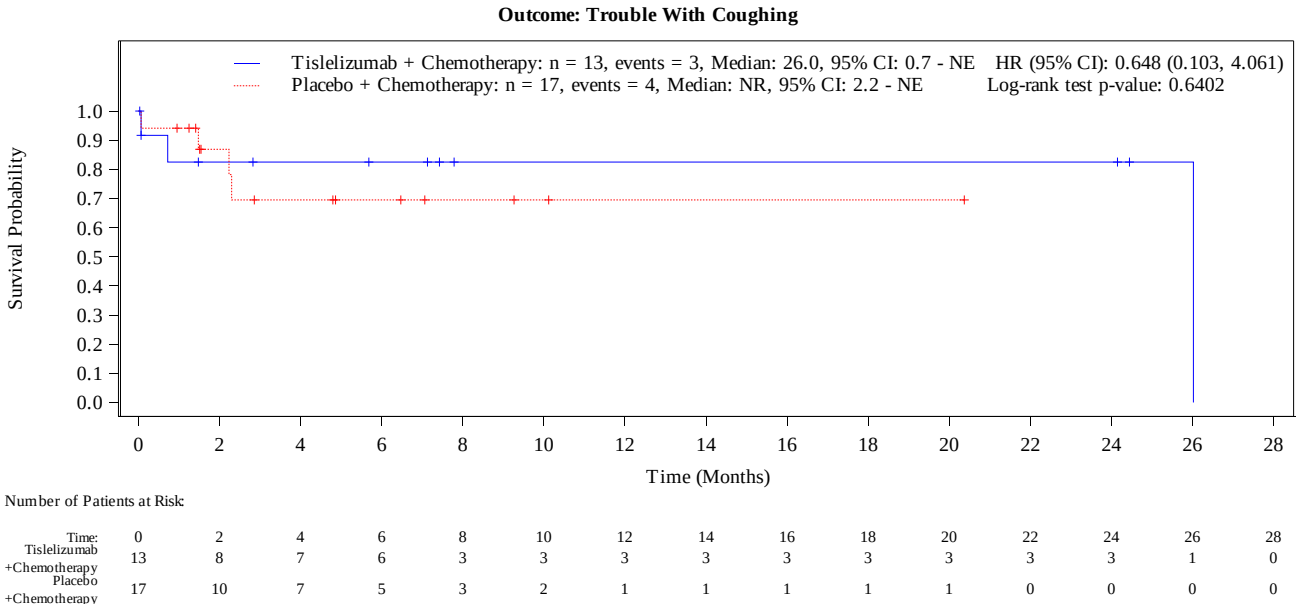

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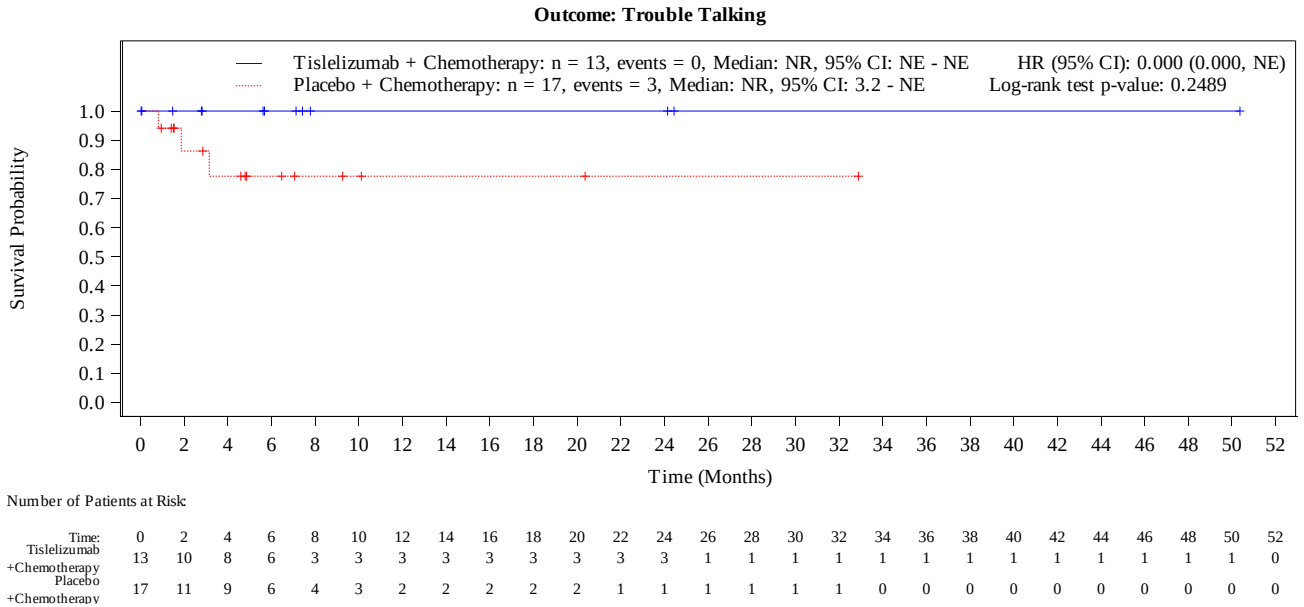

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-2-2-km-qs-oes-pop1-3y.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	5 (55.6)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	4 (36.4)	--	--	--
Female	4	3 (75.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	2 (20.0)	--	--	--
1	6	3 (50.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	3 (42.9)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	5 (45.5)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-3y.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	4 (57.1)	--	--	--
No	9	1 (11.1)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-3y.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-3y.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	1 (11.1)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-3y.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-3y.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

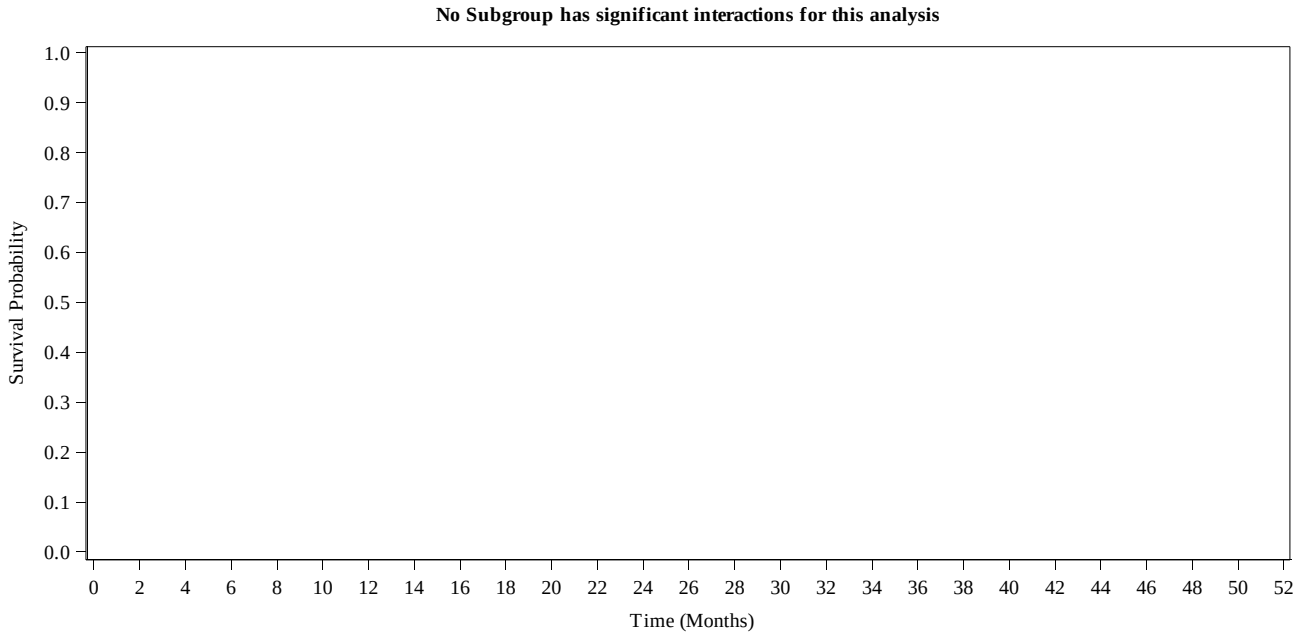
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-3y.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-2-2-s-km-tteqs-subgrp-oes-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	70.6 (26.11)		64.8 (19.76)	
	Median	77.0		69.0	
	Q1, Q3	51.0, 90.0		51.0, 80.0	
	Min, Max	13, 98		20, 92	
Cycle 2	n	10	10	15	15
	Mean (SD)	77.7 (17.80)	7.4 (29.15)	67.8 (19.24)	3.7 (15.57)
	Median	80.0	2.0	75.0	5.0
	Q1, Q3	76.0, 89.0	-10.0, 13.0	61.0, 80.0	-9.0, 15.0
	Min, Max	40, 98	-39, 63	20, 88	-23, 28
Cycle 3	n	10	10	12	12
	Mean (SD)	79.2 (12.62)	8.9 (20.30)	69.1 (23.00)	2.5 (20.25)
	Median	81.0	6.0	75.5	2.0
	Q1, Q3	69.0, 90.0	-8.0, 15.0	65.0, 84.0	-9.5, 19.5
	Min, Max	59, 95	-10, 47	20, 95	-33, 27

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	78.4 (18.41)	9.1 (16.47)	65.8 (22.06)	-0.8 (20.74)
	Median	80.0	8.0	75.0	-0.5
	Q1, Q3	79.0, 92.0	-3.0, 17.0	55.0, 80.0	-17.5, 16.0
	Min, Max	39, 96	-11, 39	21, 91	-31, 35
Cycle 5	n	8	8	11	11
	Mean (SD)	80.9 (14.97)	9.4 (17.34)	72.0 (16.73)	3.9 (20.78)
	Median	85.0	9.0	75.0	4.0
	Q1, Q3	74.5, 90.0	-6.5, 22.0	70.0, 80.0	-10.0, 23.0
	Min, Max	50, 98	-11, 37	31, 100	-30, 35
Cycle 6	n	8	8	9	9
	Mean (SD)	79.9 (16.00)	8.4 (16.29)	73.0 (19.69)	1.9 (22.62)
	Median	84.0	8.5	76.0	0.0
	Q1, Q3	72.5, 90.5	-7.5, 20.0	70.0, 80.0	-12.0, 24.0
	Min, Max	48, 97	-10, 35	27, 100	-34, 31

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	80.6 (19.26)	9.6 (15.74)	81.3 (9.23)	6.0 (16.64)
	Median	87.0	5.0	80.0	0.0
	Q1, Q3	75.0, 95.0	-3.0, 27.0	79.0, 81.0	-9.0, 20.0
	Min, Max	40, 95	-8, 34	69, 100	-12, 35
Cycle 10	n	4	4	6	6
	Mean (SD)	79.0 (27.22)	18.5 (18.16)	78.7 (15.33)	4.2 (22.66)
	Median	88.0	16.0	80.0	4.0
	Q1, Q3	60.5, 97.5	3.5, 33.5	79.0, 81.0	-10.0, 21.0
	Min, Max	40, 100	2, 40	52, 100	-29, 35
Cycle 12	n	3	3	5	5
	Mean (SD)	63.7 (25.11)	13.0 (18.52)	79.0 (13.06)	8.0 (24.58)
	Median	61.0	20.0	79.0	7.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	75.0, 86.0	-11.0, 30.0
	Min, Max	40, 90	-8, 27	60, 95	-21, 35

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	77.7 (22.23)	27.0 (30.81)	76.3 (6.35)	3.0 (16.09)
	Median	90.0	39.0	80.0	1.0
	Q1, Q3	52.0, 91.0	-8.0, 50.0	69.0, 80.0	-12.0, 20.0
	Min, Max	52, 91	-8, 50	69, 80	-12, 20
Cycle 16	n	3	3	2	2
	Mean (SD)	71.0 (19.00)	20.3 (24.95)	74.0 (7.07)	-11.5 (0.71)
	Median	71.0	30.0	74.0	-11.5
	Q1, Q3	52.0, 90.0	-8.0, 39.0	69.0, 79.0	-12.0, -11.0
	Min, Max	52, 90	-8, 39	69, 79	-12, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	63.3 (25.17)	12.7 (18.34)	76.7 (5.77)	-6.7 (6.66)
	Median	60.0	19.0	80.0	-10.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	70.0, 80.0	-11.0, 1.0
	Min, Max	40, 90	-8, 27	70, 80	-11, 1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	75.0 (21.79)	24.3 (28.22)	80.3 (0.58)	-3.0 (6.08)
	Median	85.0	37.0	80.0	0.0
	Q1, Q3	50.0, 90.0	-8.0, 44.0	80.0, 81.0	-10.0, 1.0
	Min, Max	50, 90	-8, 44	80, 81	-10, 1
Cycle 22	n	3	3	3	3
	Mean (SD)	70.3 (30.01)	19.7 (15.37)	76.3 (7.23)	-7.0 (13.08)
	Median	71.0	27.0	80.0	-1.0
	Q1, Q3	40.0, 100.0	2.0, 30.0	68.0, 81.0	-22.0, 2.0
	Min, Max	40, 100	2, 30	68, 81	-22, 2
Cycle 24	n	2	2	3	3
	Mean (SD)	86.0 (7.07)	16.5 (33.23)	78.0 (7.21)	-5.3 (13.05)
	Median	86.0	16.5	80.0	-1.0
	Q1, Q3	81.0, 91.0	-7.0, 40.0	70.0, 84.0	-20.0, 5.0
	Min, Max	81, 91	-7, 40	70, 84	-20, 5

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	3	3	3	3
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	81.7 (3.79)	-1.7 (2.52)
	Median	71.0	30.0	80.0	-2.0
	Q1, Q3	50.0, 90.0	-8.0, 37.0	79.0, 86.0	-4.0, 1.0
	Min, Max	50, 90	-8, 37	79, 86	-4, 1
Cycle 28	n	3	3	2	2
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	80.5 (13.44)	-5.0 (19.80)
	Median	71.0	30.0	80.5	-5.0
	Q1, Q3	50.0, 90.0	-8.0, 37.0	71.0, 90.0	-19.0, 9.0
	Min, Max	50, 90	-8, 37	71, 90	-19, 9
Cycle 30	n	2	2	2	2
	Mean (SD)	65.5 (21.92)	38.5 (2.12)	79.5 (0.71)	-6.0 (7.07)
	Median	65.5	38.5	79.5	-6.0
	Q1, Q3	50.0, 81.0	37.0, 40.0	79.0, 80.0	-11.0, -1.0
	Min, Max	50, 81	37, 40	79, 80	-11, -1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	74.3 (20.60)	23.7 (27.47)	81.0 (NE)	-9.0 (NE)
	Median	82.0	38.0	81.0	-9.0
	Q1, Q3	51.0, 90.0	-8.0, 41.0	81.0, 81.0	-9.0, -9.0
	Min, Max	51, 90	-8, 41	81, 81	-9, -9
Cycle 34	n	3	3	1	1
	Mean (SD)	76.3 (25.70)	25.7 (20.55)	87.0 (NE)	-3.0 (NE)
	Median	80.0	36.0	87.0	-3.0
	Q1, Q3	49.0, 100.0	2.0, 39.0	87.0, 87.0	-3.0, -3.0
	Min, Max	49, 100	2, 39	87, 87	-3, -3
Cycle 36	n	2	2	1	1
	Mean (SD)	69.5 (28.99)	14.0 (31.11)	70.0 (NE)	-20.0 (NE)
	Median	69.5	14.0	70.0	-20.0
	Q1, Q3	49.0, 90.0	-8.0, 36.0	70.0, 70.0	-20.0, -20.0
	Min, Max	49, 90	-8, 36	70, 70	-20, -20

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	1	1	1	1
	Mean (SD)	48.0 (NE)	35.0 (NE)	95.0 (NE)	5.0 (NE)
	Median	48.0	35.0	95.0	5.0
	Q1, Q3	48.0, 48.0	35.0, 35.0	95.0, 95.0	5.0, 5.0
	Min, Max	48, 48	35, 35	95, 95	5, 5
Cycle 40	n	0	0	1	1
	Mean (SD)			70.0 (NE)	-20.0 (NE)
	Median			70.0	-20.0
	Q1, Q3			70.0, 70.0	-20.0, -20.0
	Min, Max			70, 70	-20, -20
Cycle 42	n	1	1	1	1
	Mean (SD)	54.0 (NE)	41.0 (NE)	70.0 (NE)	-20.0 (NE)
	Median	54.0	41.0	70.0	-20.0
	Q1, Q3	54.0, 54.0	41.0, 41.0	70.0, 70.0	-20.0, -20.0
	Min, Max	54, 54	41, 41	70, 70	-20, -20

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	1	1	1	1
	Mean (SD)	48.0 (NE)	35.0 (NE)	65.0 (NE)	-25.0 (NE)
	Median	48.0	35.0	65.0	-25.0
	Q1, Q3	48.0, 48.0	35.0, 35.0	65.0, 65.0	-25.0, -25.0
	Min, Max	48, 48	35, 35	65, 65	-25, -25
Cycle 46	n	1	1	1	1
	Mean (SD)	40.0 (NE)	27.0 (NE)	55.0 (NE)	-35.0 (NE)
	Median	40.0	27.0	55.0	-35.0
	Q1, Q3	40.0, 40.0	27.0, 27.0	55.0, 55.0	-35.0, -35.0
	Min, Max	40, 40	27, 27	55, 55	-35, -35
Cycle 48	n	1	1	0	0
	Mean (SD)	60.0 (NE)	47.0 (NE)		
	Median	60.0	47.0		
	Q1, Q3	60.0, 60.0	47.0, 47.0		
	Min, Max	60, 60	47, 47		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	48.0 (NE)	35.0 (NE)		
	Median	48.0	35.0		
	Q1, Q3	48.0, 48.0	35.0, 35.0		
	Min, Max	48, 48	35, 35		
Cycle 52	n	1	1	0	0
	Mean (SD)	58.0 (NE)	45.0 (NE)		
	Median	58.0	45.0		
	Q1, Q3	58.0, 58.0	45.0, 45.0		
	Min, Max	58, 58	45, 45		
Cycle 54	n	1	1	0	0
	Mean (SD)	51.0 (NE)	38.0 (NE)		
	Median	51.0	38.0		
	Q1, Q3	51.0, 51.0	38.0, 38.0		
	Min, Max	51, 51	38, 38		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 56	n	1	1	0	0
	Mean (SD)	70.0 (NE)	57.0 (NE)		
	Median	70.0	57.0		
	Q1, Q3	70.0, 70.0	57.0, 57.0		
	Min, Max	70, 70	57, 57		
Cycle 58	n	1	1	0	0
	Mean (SD)	44.0 (NE)	31.0 (NE)		
	Median	44.0	31.0		
	Q1, Q3	44.0, 44.0	31.0, 31.0		
	Min, Max	44, 44	31, 31		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.0 (NE)	53.0 (NE)		
	Median	66.0	53.0		
	Q1, Q3	66.0, 66.0	53.0, 53.0		
	Min, Max	66, 66	53, 53		

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 62	n	1	1	0	0
	Mean (SD)	60.0 (NE)	47.0 (NE)		
	Median	60.0	47.0		
	Q1, Q3	60.0, 60.0	47.0, 47.0		
	Min, Max	60, 60	47, 47		
Cycle 64	n	1	1	0	0
	Mean (SD)	52.0 (NE)	39.0 (NE)		
	Median	52.0	39.0		
	Q1, Q3	52.0, 52.0	39.0, 39.0		
	Min, Max	52, 52	39, 39		
End of Treatment	n	9	9	16	16
	Mean (SD)	68.8 (25.21)	-7.4 (32.80)	63.8 (24.73)	-2.6 (17.47)
	Median	77.0	-8.0	70.0	-1.5
	Q1, Q3	60.0, 82.0	-13.0, 8.0	50.0, 76.5	-12.0, 9.5
	Min, Max	10, 94	-80, 41	10, 100	-40, 25

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	59.4 (25.75)	-11.2 (26.27)	54.7 (19.95)	-10.1 (18.17)
	Median	60.5	-8.0	60.0	-3.0
	Q1, Q3	40.0, 80.0	-11.5, 1.0	49.0, 67.0	-26.0, 2.0
	Min, Max	10, 94	-80, 26	10, 85	-40, 15

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:56 t-14-2-6-5-1-qs-chg-eq5d-pop1-3y.rtf

Table 14.2.6.5.1.1:
EQ-5D-VAS: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
EQ-5D VAS									
Cycle 6	8		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	70.58 (26.11)	5.88 (4.76)	17	64.76 (19.76)	3.75 (3.66)	2.13 (-8.79, 13.05)	0.17 (-0.68, 1.01)	0.6902

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+ chemotherapy arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-mmrmqs.sas 21OCT2024 08:40 t-14-2-6-5-1-1-eff-mmrmqs-vas-pop1-3y.rtf

Table 14.2.6.5.1.2:
Analyses of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	13	1 (7.7)	NR (NE, NE)	17	4 (23.5)	14.7 (3.2, NE)	0.636 (0.066, 6.122)	0.6928

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

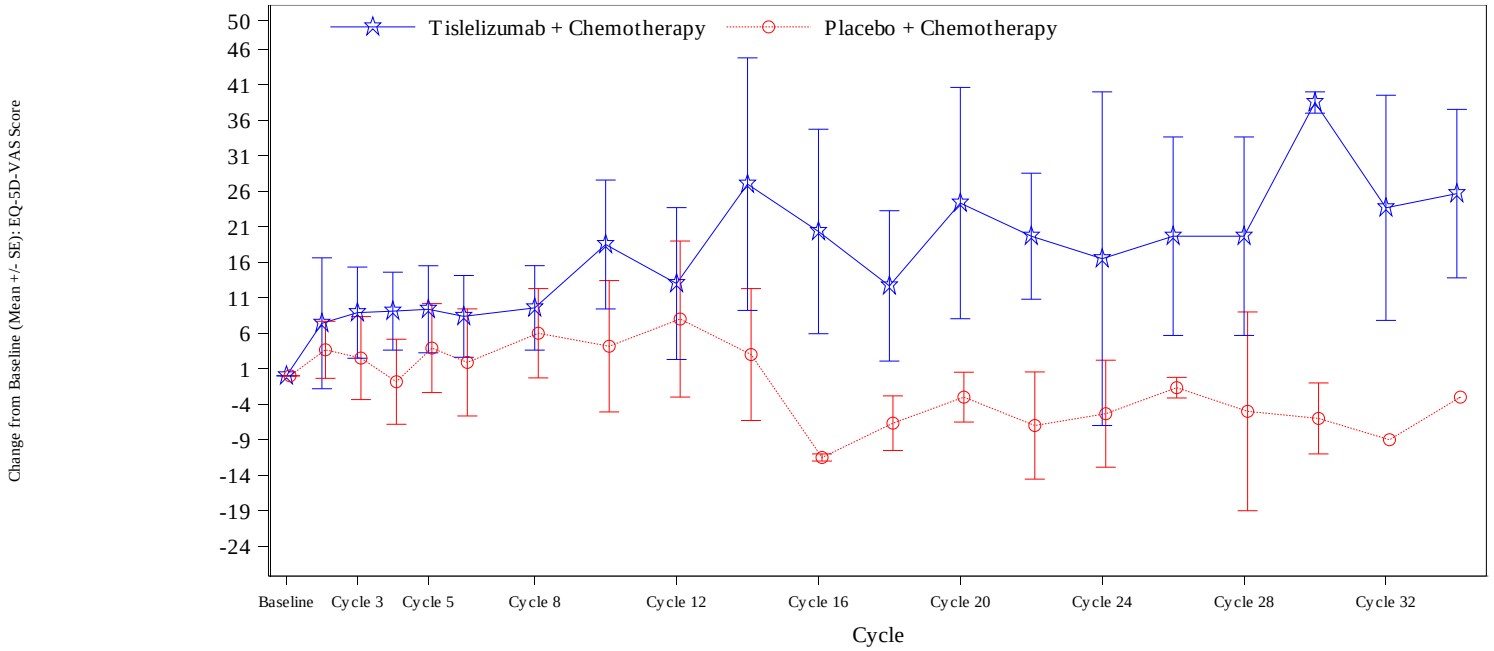
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tte-qlq.sas 21OCT2024 08:56 t-14-2-6-5-1-2-eff-tte-qlq-vas-pop1-3y.rtf

Figure 14.2.7.4:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

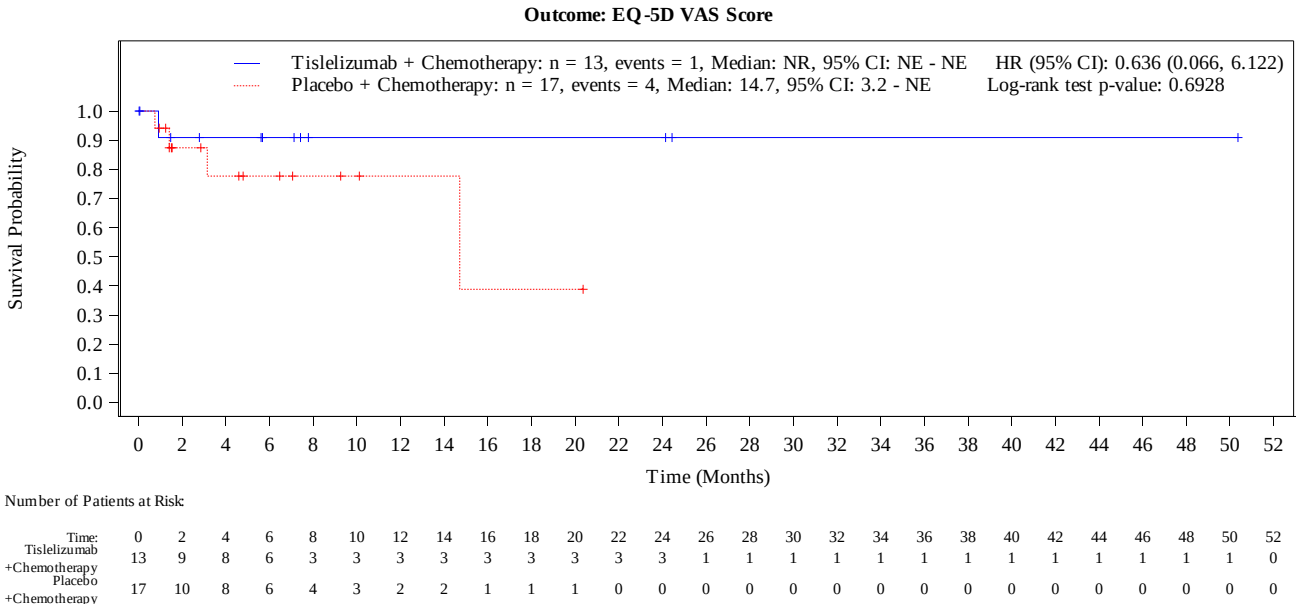


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	8	7	4	3	3	3	3	3	3	2	3	3	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-series.sas 26NOV2024 21:59 f-14-2-7-4-series-eq5d-pop1-3y.rtf

Figure 14.2.7.4.2:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-qs.sas 05NOV2024 00:21 f-14-2-7-4-2-km-qs-vas-pop1-3y.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

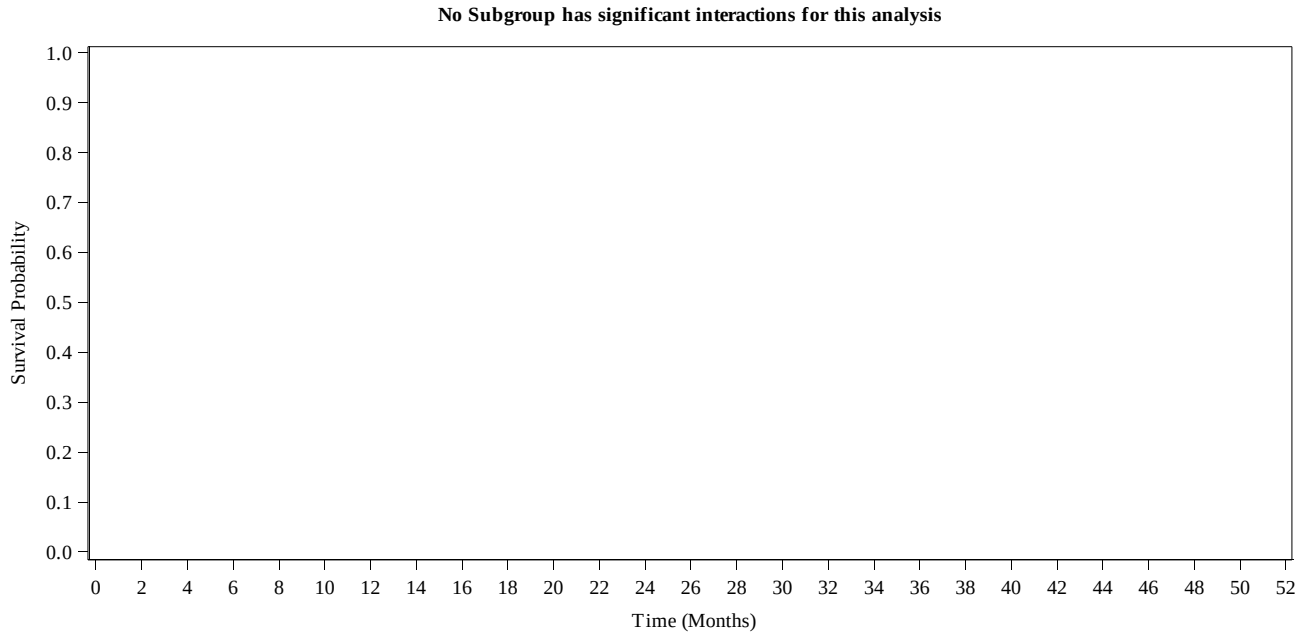
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 21OCT2024 08:57 t-14-2-6-5-1-2-s-eff-tteqs-subgrp-vas-pop1-3y.rtf

Figure 14.2.7.4.2.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 21OCT2024 23:39 f-14-2-7-4-2-s-km-tteqs-subgrp-vas-pop1-3y.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Patients with Any Subsequent Anti-Cancer Therapy, n (%)	9 (69.2)	13 (76.5)
Radiotherapy	2 (15.4)	6 (35.3)
Procedure or Surgery	1 (7.7)	2 (11.8)
Systemic Therapy	9 (69.2)	12 (70.6)
Immunotherapy	4 (30.8)	7 (41.2)
Time to First Post-Treatment Anti-Cancer Therapy (months)		
n	9	13
Mean (SD)	2.08 (1.986)	2.05 (2.757)
Median	0.99	1.61
Q1, Q3	0.79, 3.32	0.56, 2.07
Min, Max	0.6, 6.0	0.3, 10.8

Source: ADCM, ADPR, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.
Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-3y.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Time to First Post-Treatment Immunotherapy (months)		
n	4	7
Mean (SD)	4.94 (5.508)	2.70 (2.322)
Median	3.45	2.63
Q1, Q3	0.69, 9.18	0.56, 4.27
Min, Max	0.6, 12.3	0.3, 6.8
Post-Treatment Anti-Cancer Therapy Duration (months)		
Systemic Therapy		
n	9	12
Mean (SD)	11.35 (7.671)	5.88 (8.097)
Median	12.52	2.99
Q1, Q3	4.40, 15.41	0.92, 7.56
Min, Max	1.2, 25.1	0.0, 28.5
Patients with Ongoing Anti-Cancer Systemic Therapy at Data Cutoff, n (%)	1 (7.7)	1 (5.9)

Source: ADCM, ADPR, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.

Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-3y.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Immunotherapy		
n	4	7
Mean (SD)	2.15 (1.988)	3.10 (3.619)
Median	1.41	1.64
Q1, Q3	0.89, 3.42	0.03, 7.62
Min, Max	0.7, 5.1	0.0, 8.9
Patients with Ongoing Immunotherapy at Data Cutoff, n (%)	0 (0.0)	0 (0.0)

Source: ADCM, ADPR, ADBASE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.
Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-byanti.sas 21OCT2024 08:29 t-14-2-8-1-byanti-pop1-3y.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Duration of Treatment (month) [a]			
n	13	17	30
Mean (SD)	13.10 (15.398)	7.58 (8.796)	9.97 (12.187)
Median	5.65	4.14	5.22
Q1, Q3	2.76, 24.11	1.58, 8.77	2.53, 10.25
Min, Max	0.7, 50.9	0.7, 32.6	0.7, 50.9
Duration of Treatment, n (%)			
< 1 month	2 (15.4)	2 (11.8)	4 (13.3)
≥ 1 to < 3 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 3 to < 6 months	3 (23.1)	4 (23.5)	7 (23.3)
≥ 6 to < 12 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 12 to < 18 months	0 (0.0)	0 (0.0)	0 (0.0)
≥ 18 to < 24 months	0 (0.0)	2 (11.8)	2 (6.7)
≥ 24 months	4 (30.8)	1 (5.9)	5 (16.7)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:37 t-14-3-1-1-1-ex-tis-pop1-3y.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Number of Cycles Received			
n	13	17	30
Mean (SD)	17.4 (19.90)	9.4 (10.85)	12.8 (15.66)
Median	8.0	5.0	7.5
Q1, Q3	4.0, 34.0	2.0, 12.0	3.0, 14.0
Min, Max	1, 64	1, 42	1, 64
Number of Cycles Received, n (%)			
1-3	3 (23.1)	7 (41.2)	10 (33.3)
4-6	1 (7.7)	3 (17.6)	4 (13.3)
7-9	4 (30.8)	1 (5.9)	5 (16.7)
10-12	1 (7.7)	2 (11.8)	3 (10.0)
13-18	0 (0.0)	2 (11.8)	2 (6.7)
19-24	0 (0.0)	0 (0.0)	0 (0.0)
25-36	2 (15.4)	1 (5.9)	3 (10.0)
>36	2 (15.4)	1 (5.9)	3 (10.0)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:37 t-14-3-1-1-1-ex-tis-pop1-3y.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Cumulative Total Dose (mg) per Patient [b]			
n	13	17	30
Mean (SD)	3476.92 (3979.563)	1870.59 (2170.186)	2566.67 (3131.633)
Median	1600.00	1000.00	1500.00
Q1, Q3	800.00, 6800.00	400.00, 2400.00	600.00, 2800.00
Min, Max	200.0, 12800.0	200.0, 8400.0	200.0, 12800.0
Actual Dose Intensity (mg/cycle) per Patient [c]			
n	13	17	30
Mean (SD)	187.76 (14.396)	178.05 (26.275)	182.26 (22.149)
Median	194.92	186.67	188.61
Q1, Q3	174.19, 198.82	171.43, 198.11	173.08, 198.82
Min, Max	161.5, 200.0	112.4, 200.0	112.4, 200.0

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:37 t-14-3-1-1-1-ex-tis-pop1-3y.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Relative Dose Intensity (%) per Patient [d]			
n	13	17	30
Mean (SD)	93.88 (7.198)	89.03 (13.137)	91.13 (11.075)
Median	97.46	93.33	94.31
Q1, Q3	87.10, 99.41	85.71, 99.06	86.54, 99.41
Min, Max	80.8, 100.0	56.2, 100.0	56.2, 100.0
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:37 t-14-3-1-1-1-ex-tis-pop1-3y.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Patients with Any Dose Modification, n (%)	8 (61.5)	11 (64.7)	19 (63.3)
Dose Delay	8 (61.5)	11 (64.7)	19 (63.3)
Adverse Event	3 (23.1)	10 (58.8)	13 (43.3)
Other	7 (53.8)	4 (23.5)	11 (36.7)
Related to COVID-19	2 (15.4)	2 (11.8)	4 (13.3)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	0 (0.0)	0 (0.0)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.

[a] Duration of treatment = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375, if patients discontinued from treatment; Duration of treatment = (cutoff date - first dose date + 1)/30.4375, if patients with ongoing treatment.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.

[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date up to cutoff date+ 21 - first dose date).

[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:37 t-14-3-1-1-1-ex-tis-pop1-3y.rtf

Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment (month) [a]				
n	13	13	17	17
Mean (SD)	4.12 (2.138)	7.21 (11.051)	3.51 (1.918)	5.08 (5.151)
Median	4.27	4.30	3.48	4.17
Q1, Q3	2.76, 4.90	2.79, 6.87	1.68, 4.40	1.71, 6.14
Min, Max	0.7, 8.3	0.7, 43.3	0.7, 7.2	0.7, 22.4

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment, n (%)				
< 1 month	2 (15.4)	2 (15.4)	2 (11.8)	2 (11.8)
≥ 1 to < 3 months	2 (15.4)	2 (15.4)	4 (23.5)	4 (23.5)
≥ 3 to < 6 months	7 (53.8)	5 (38.5)	9 (52.9)	6 (35.3)
≥ 6 to < 12 months	2 (15.4)	3 (23.1)	2 (11.8)	4 (23.5)
≥ 12 to ≤ 18 months	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
> 18 months	0 (0.0)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received				
n	13	13	17	17
Mean (SD)	5.5 (2.67)	9.1 (12.89)	4.5 (2.45)	5.9 (4.55)
Median	6.0	6.0	5.0	5.0
Q1, Q3	4.0, 6.0	4.0, 8.0	2.0, 6.0	2.0, 8.0
Min, Max	1, 10	1, 51	1, 9	1, 17

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received, n (%)				
1-3	3 (23.1)	3 (23.1)	7 (41.2)	7 (41.2)
4-6	7 (53.8)	5 (38.5)	7 (41.2)	4 (23.5)
7-9	2 (15.4)	3 (23.1)	3 (17.6)	3 (17.6)
10-12	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)
13-18	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
>18	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Cumulative Total Dose (mg/m^2) per Patient [b]				
n	13	13	17	17
Mean (SD)	356.59 (173.633)	35771.80 (53377.563)	289.96 (155.327)	21636.25 (17662.020)
Median	359.07	22461.80	296.93	19909.72
Q1, Q3	276.36, 451.08	16162.38, 31793.25	164.68, 402.36	8162.99, 26944.39
Min, Max	71.9, 648.8	3671.0, 209891.7	59.9, 556.6	3749.5, 68382.0

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Actual Dose Intensity (mg/m^2/cycle) per Patient [c]				
n	13	13	17	17
Mean (SD)	62.39 (12.288)	3512.76 (363.810)	59.38 (12.483)	3169.15 (642.132)
Median	59.84	3504.12	58.30	3485.46
Q1, Q3	53.85, 73.42	3344.25, 3712.21	50.12, 67.03	2710.97, 3665.54
Min, Max	38.2, 80.6	2695.7, 3993.1	41.3, 82.3	2102.5, 3986.6

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Relative Dose Intensity (%) per Patient [d]				
n	13	13	17	17
Mean (SD)	87.64 (16.755)	90.53 (9.771)	82.39 (16.600)	79.75 (16.536)
Median	96.97	93.44	84.41	78.65
Q1, Q3	84.77, 99.22	83.86, 98.68	68.89, 97.17	67.77, 95.44
Min, Max	47.7, 100.7	67.4, 99.8	54.2, 102.9	52.6, 99.7
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	0 (0.0)	1 (5.9)	2 (11.8)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Patients with Any Dose Modification, n (%)	7 (53.8)	8 (61.5)	12 (70.6)	14 (82.4)
Dose Delay	7 (53.8)	7 (53.8)	9 (52.9)	10 (58.8)
Adverse Event	5 (38.5)	4 (30.8)	8 (47.1)	8 (47.1)
Other	3 (23.1)	5 (38.5)	1 (5.9)	3 (17.6)
Related to COVID-19	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	3 (23.1)	0 (0.0)	7 (41.2)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
Other	0 (0.0)	3 (23.1)	0 (0.0)	6 (35.3)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.
[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.
[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.
[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Dose Reduction	4 (30.8)	2 (15.4)	11 (64.7)	8 (47.1)
Adverse Event	4 (30.8)	2 (15.4)	9 (52.9)	8 (47.1)
Other	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date, cutoff date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date, cutoff date) - first dose date + 1)/30.4375. Duration of treatment (TD) for patients with ongoing treatment: TD = (cutoff date - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date up to cutoff date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date up to cutoff date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	13	13 (100.0)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.1)	0.420 (0.145, 1.218)	0.1047
TEAE >= Grade 3	13	10 (76.9)	0.9 (0.2, 7.1)	17	14 (82.4)	1.0 (0.2, 2.1)	0.936 (0.313, 2.795)	0.9373
Serious TEAE	13	4 (30.8)	NR (5.0, NE)	17	6 (35.3)	20.5 (0.3, NE)	1.033 (0.245, 4.359)	0.9650
TEAE Leading to Treatment Discontinuation	13	2 (15.4)	NR (NE, NE)	17	6 (35.3)	NR (3.9, NE)	1.071 (0.177, 6.472)	0.9406

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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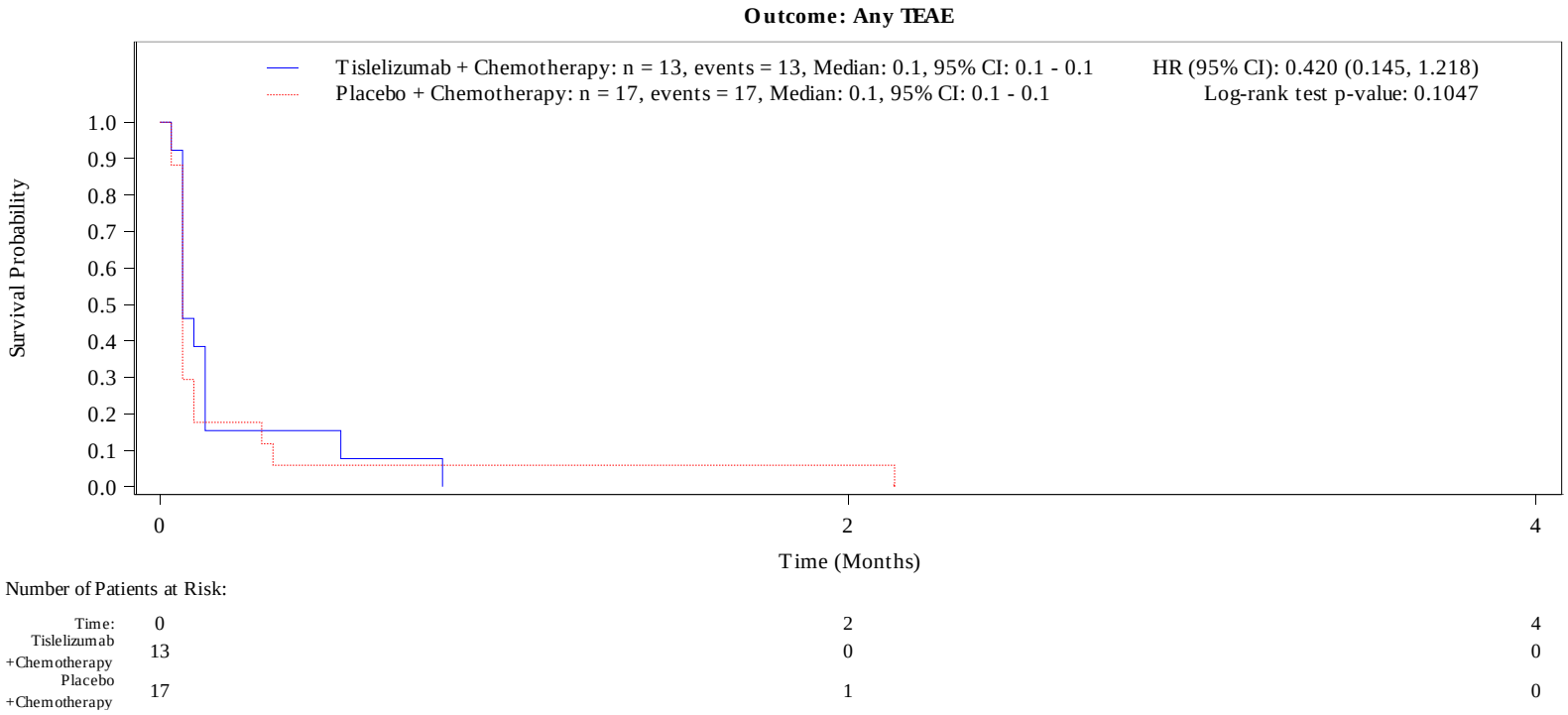
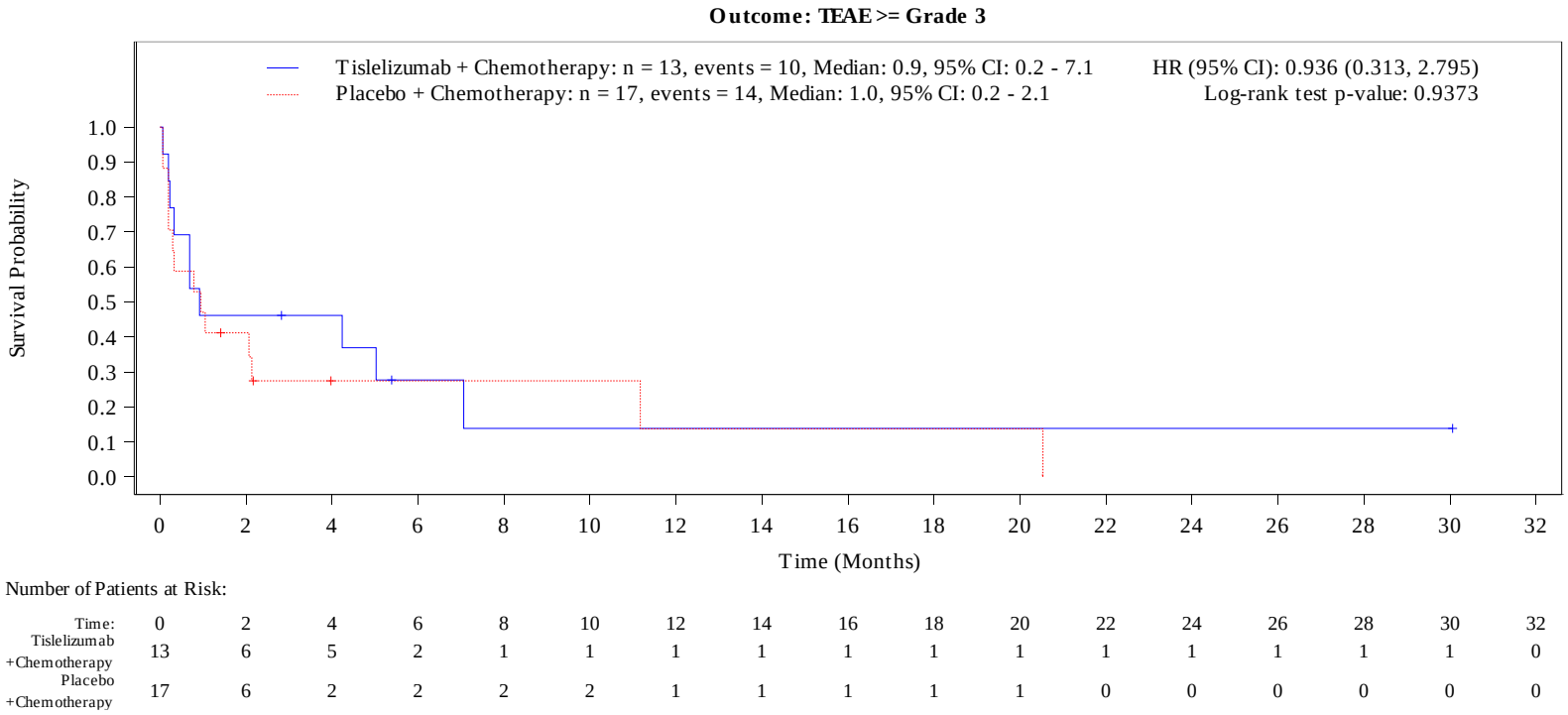
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-3y.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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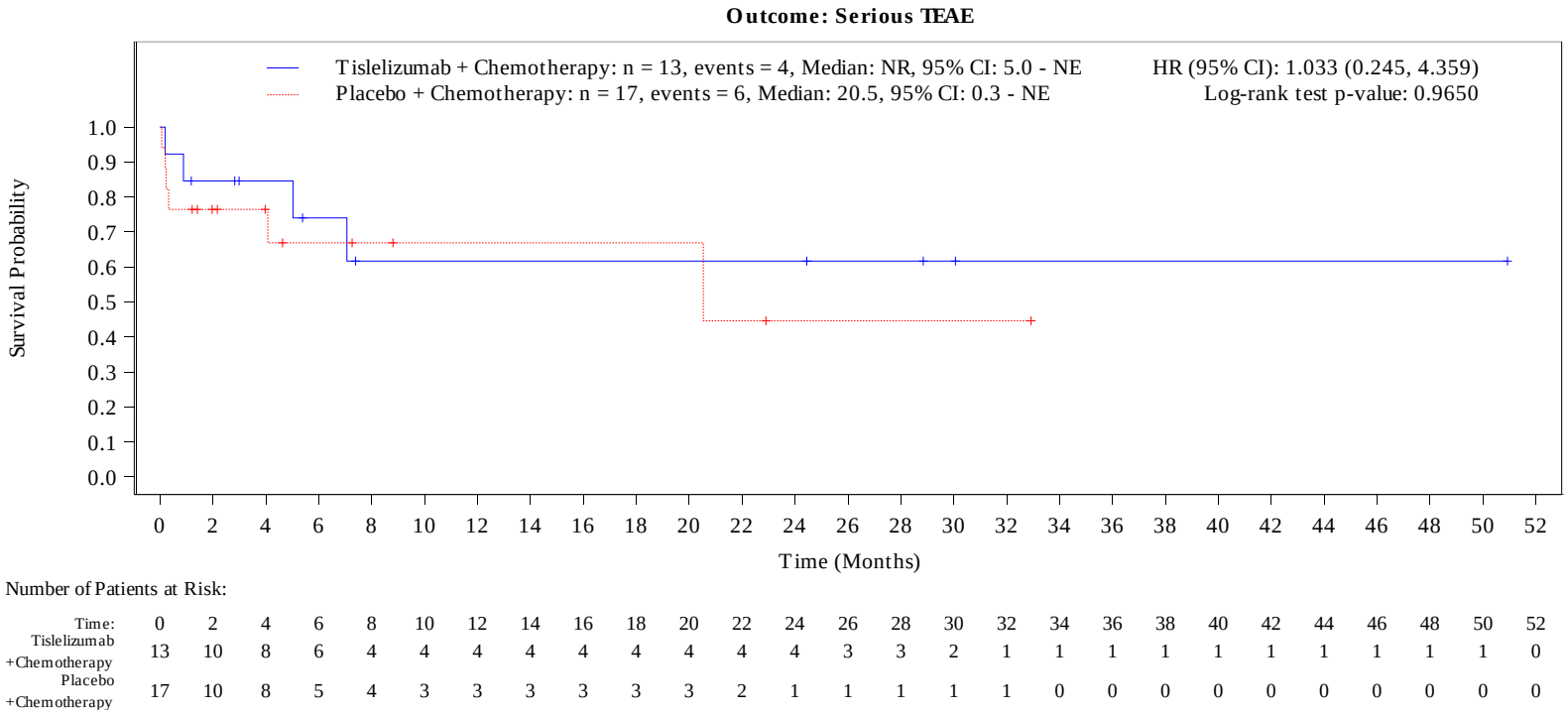
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	10	8	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	10	8	5	4	3	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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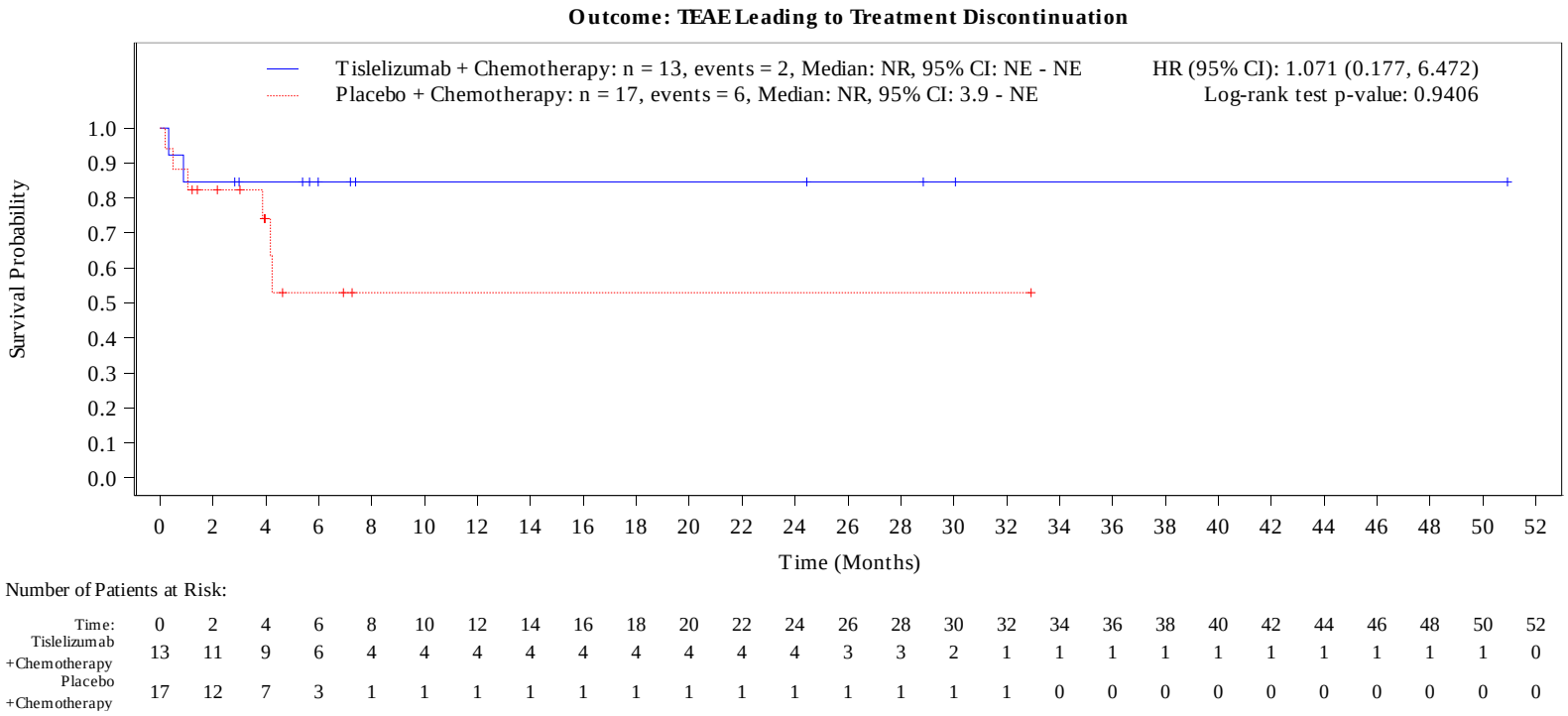
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-tteae.sas 21OCT2024 23:38 f-14-3-1-1-km-tteae-pop1-3y.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	9 (100.0)	0.1 (0.0, 0.5)	8	8 (100.0)	0.1 (0.0, 0.3)	0.890 (0.323, 2.454)	0.9808
Age >= 65	4	4 (100.0)	0.1 (0.1, NE)	9	9 (100.0)	0.1 (0.0, 0.1)	1.052 (0.294, 3.762)	0.9825
Interaction								0.8740

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-tteae-subgrp.sas 21OCT2024 09:21 t-14-3-1-2-1-1-s-tteae-subgrp-pop1-3y.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	9 (100.0)	0.1 (0.1, 0.1)	11	11 (100.0)	0.1 (0.0, 0.1)	0.700 (0.275, 1.782)	0.3126
Female	4	4 (100.0)	0.1 (0.0, NE)	6	6 (100.0)	0.1 (0.1, NE)	0.971 (0.244, 3.866)	0.6939
Interaction								0.7957

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	7 (100.0)	0.1 (0.1, 0.1)	10	10 (100.0)	0.1 (0.0, 0.1)	0.275 (0.076, 0.991)	0.0233
1	6	6 (100.0)	0.1 (0.0, NE)	7	7 (100.0)	0.1 (0.1, 0.3)	1.474 (0.465, 4.673)	0.4652
Interaction								0.0384

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.1 (0.1, NE)	7	7 (100.0)	0.1 (0.0, 0.1)	0.468 (0.107, 2.057)	0.2016
No	9	9 (100.0)	0.1 (0.0, 0.5)	10	10 (100.0)	0.1 (0.1, 0.3)	0.986 (0.384, 2.530)	0.9089
Interaction								0.4597

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	6 (66.7)	4.2 (0.1, NE)	8	6 (75.0)	2.1 (0.3, NE)	1.002 (0.318, 3.157)	0.9984
Age >= 65	4	4 (100.0)	0.7 (0.2, NE)	9	8 (88.9)	0.2 (0.1, 1.0)	0.586 (0.153, 2.239)	0.4168
Interaction								0.4084

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	8 (88.9)	0.7 (0.2, NE)	11	9 (81.8)	1.0 (0.2, NE)	1.072 (0.397, 2.898)	0.8967
Female	4	2 (50.0)	4.2 (0.1, NE)	6	5 (83.3)	0.9 (0.1, NE)	0.445 (0.084, 2.365)	0.3195
Interaction								0.3981

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	0.7 (0.2, NE)	10	9 (90.0)	0.9 (0.1, 2.1)	0.887 (0.304, 2.593)	0.8329
1	6	4 (66.7)	2.6 (0.1, NE)	7	5 (71.4)	1.0 (0.1, NE)	0.831 (0.217, 3.183)	0.7833
Interaction								0.9489

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.5 (0.1, NE)	7	6 (85.7)	0.8 (0.1, NE)	1.481 (0.387, 5.667)	0.5460
No	9	6 (66.7)	4.2 (0.2, NE)	10	8 (80.0)	1.6 (0.2, NE)	0.654 (0.222, 1.924)	0.4392
Interaction								0.4606

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	3 (33.3)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	1 (14.3)	--	--	--
No	9	1 (11.1)	--	10	5 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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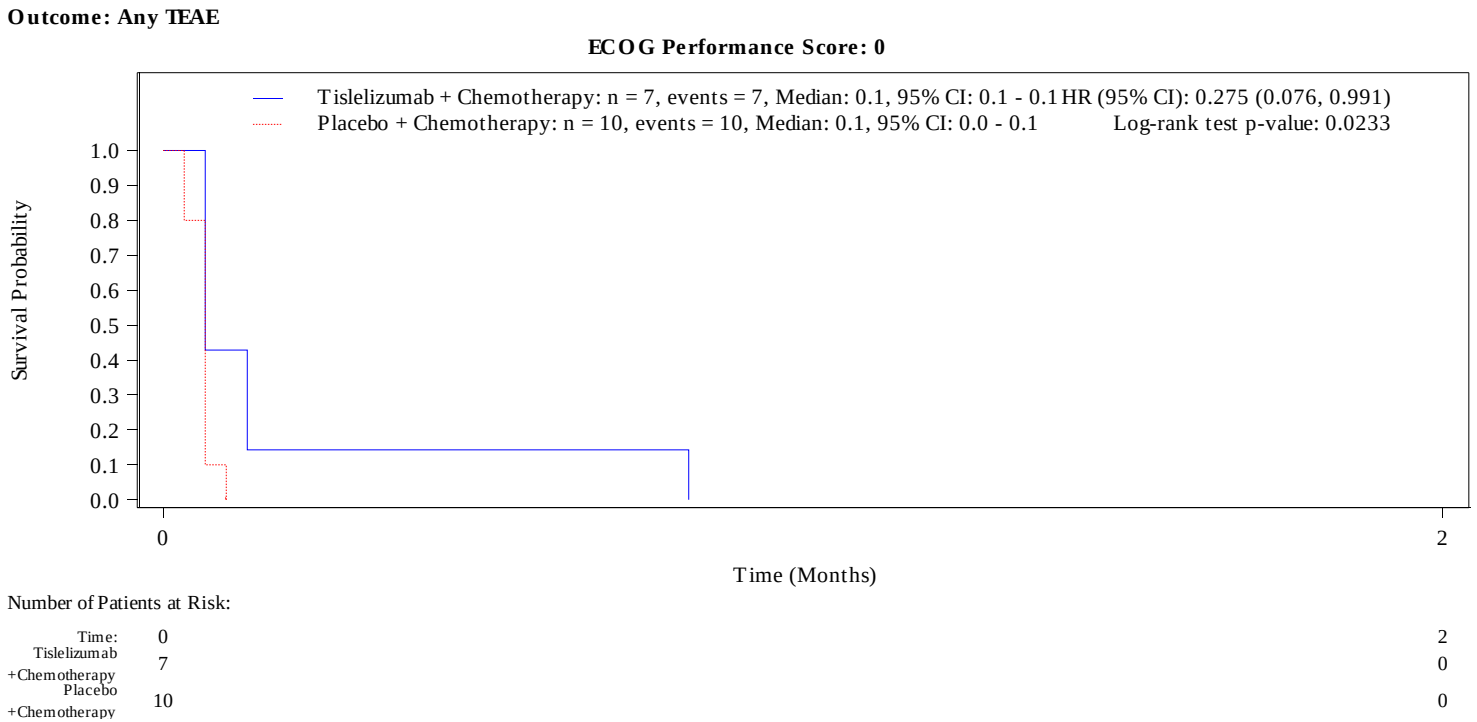
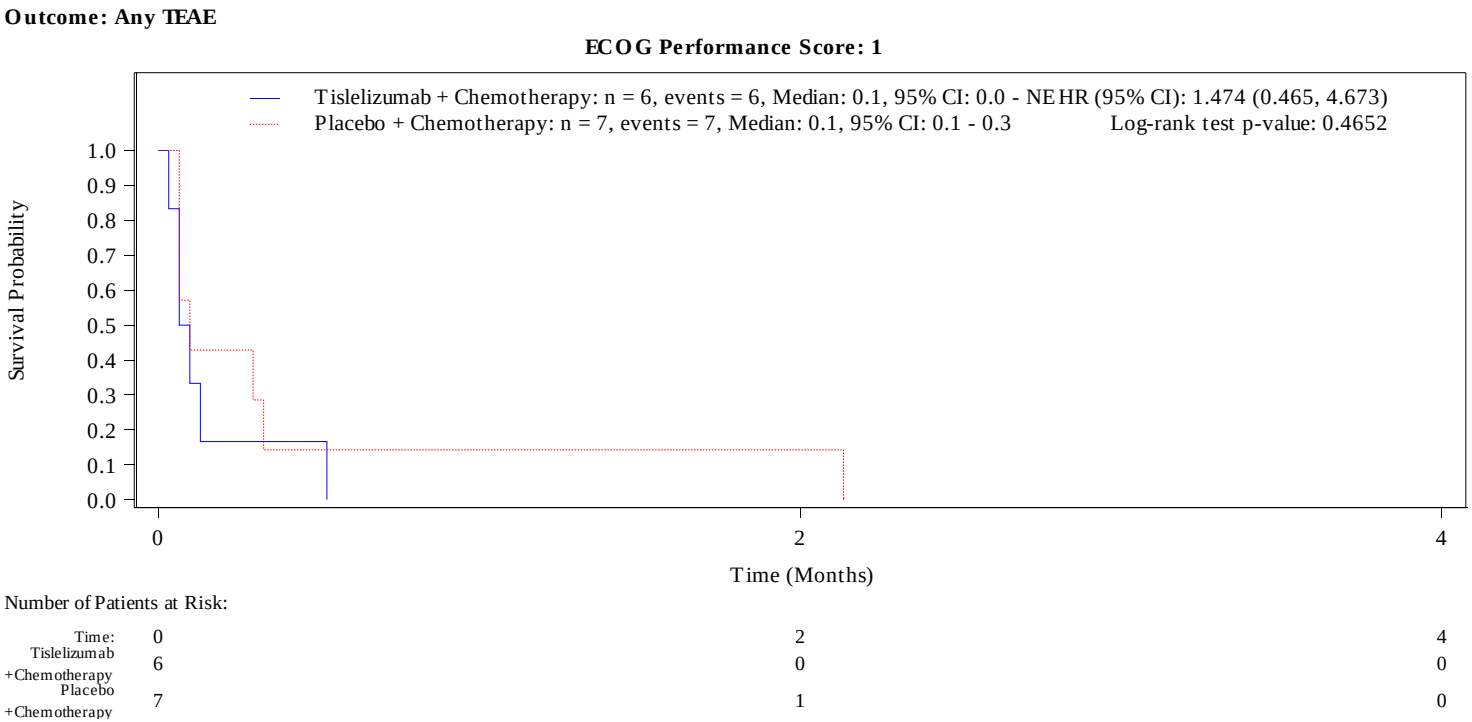
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	8 (61.5)	1.4 (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	4.057 (0.957, 17.200)	0.0451
Anaemia	13	6 (46.2)	NR (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	3.407 (0.772, 15.033)	0.0923
Leukopenia	13	2 (15.4)	NR (1.3, NE)	17	1 (5.9)	NR (NE, NE)	2.442 (0.202, 29.535)	0.4712
Neutropenia	13	3 (23.1)	NR (1.4, NE)	17	3 (17.6)	NR (5.0, NE)	2.435 (0.367, 16.158)	0.3451
Endocrine disorders	13	2 (15.4)	NR (4.2, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3008
Gastrointestinal disorders	13	11 (84.6)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.2)	1.027 (0.408, 2.589)	0.9873

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Constipation	13	9 (69.2)	0.8 (0.1, NE)	17	9 (52.9)	0.9 (0.1, NE)	0.606 (0.201, 1.833)	0.4122
Diarrhoea	13	4 (30.8)	36.1 (3.5, NE)	17	7 (41.2)	15.7 (0.8, NE)	1.092 (0.216, 5.529)	0.9152
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (20.5, NE)	NE (NE, NE)	NE
Nausea	13	5 (38.5)	NR (0.1, NE)	17	9 (52.9)	0.8 (0.1, NE)	0.775 (0.237, 2.530)	0.6705
Stomatitis	13	5 (38.5)	NR (0.2, NE)	17	7 (41.2)	NR (0.4, NE)	1.091 (0.260, 4.580)	0.9449
General disorders and administration site conditions	13	7 (53.8)	1.7 (0.1, NE)	17	12 (70.6)	0.2 (0.1, NE)	0.588 (0.216, 1.600)	0.3153

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Asthenia	13	2 (15.4)	50.4 (NE, NE)	17	4 (23.5)	NR (1.2, NE)	0.592 (0.062, 5.654)	0.6573
Fatigue	13	2 (15.4)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.493 (0.078, 3.128)	0.4453
Generalised oedema	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Malaise	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.345 (0.034, 3.496)	0.3486
Pyrexia	13	2 (15.4)	NR (3.9, NE)	17	4 (23.5)	NR (12.3, NE)	1.204 (0.161, 8.988)	0.8560
Infections and infestations	13	5 (38.5)	9.4 (1.5, NE)	17	5 (29.4)	17.5 (7.2, NE)	3.558 (0.574, 22.063)	0.1560

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia	13	2 (15.4)	NR (11.9, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urinary tract infection	13	1 (7.7)	NR (3.3, NE)	17	2 (11.8)	NR (15.1, NE)	>999.99 (0.000, NE)	0.4497
Injury, poisoning and procedural complications	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336
Fall	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	13	10 (76.9)	0.7 (0.5, 4.2)	17	8 (47.1)	5.1 (0.5, NE)	1.161 (0.387, 3.481)	0.7769
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.243 (0.022, 2.711)	0.2283

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood creatinine increased	13	2 (15.4)	NR (1.4, NE)	17	2 (11.8)	NR (4.0, NE)	0.762 (0.100, 5.803)	0.7921
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.406 (0.089, 1.851)	0.2311
Platelet count decreased	13	4 (30.8)	NR (2.9, NE)	17	1 (5.9)	32.9 (NE, NE)	>999.99 (0.000, NE)	0.0757
Weight decreased	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (5.1, NE)	0.712 (0.063, 8.022)	0.7822
White blood cell count decreased	13	4 (30.8)	NR (4.2, NE)	17	6 (35.3)	NR (1.6, NE)	0.204 (0.039, 1.080)	0.0415

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	13	10 (76.9)	1.8 (0.5, NE)	17	9 (52.9)	6.5 (0.5, NE)	1.352 (0.454, 4.025)	0.5963
Decreased appetite	13	7 (53.8)	6.7 (0.8, NE)	17	4 (23.5)	NR (6.7, NE)	2.575 (0.588, 11.282)	0.1983
Hyperglycaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1614
Hyperuricaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1086
Hypokalaemia	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.555 (0.056, 5.515)	0.6104
Hyponatraemia	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.614 (0.052, 7.308)	0.6974
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1614

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	14.6 (9.3, NE)	2.236 (0.111, 44.877)	0.5930
Nervous system disorders	13	3 (23.1)	46.0 (5.4, NE)	17	9 (52.9)	3.3 (0.3, NE)	0.211 (0.041, 1.086)	0.0461
Dysgeusia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Headache	13	2 (15.4)	49.0 (NE, NE)	17	1 (5.9)	NR (NE, NE)	1.118 (0.062, 20.117)	0.9397
Peripheral sensory neuropathy	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.3, NE)	0.700 (0.100, 4.925)	0.7195

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Psychiatric disorders	13	2 (15.4)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072
Insomnia	13	1 (7.7)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072
Renal and urinary disorders	13	1 (7.7)	NR (4.7, NE)	17	5 (29.4)	NR (2.8, NE)	0.176 (0.019, 1.637)	0.0892
Chronic kidney disease	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Renal impairment	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.2, NE)	0.000 (0.000, NE)	0.0564
Respiratory, thoracic and mediastinal disorders	13	6 (46.2)	6.2 (1.1, NE)	17	9 (52.9)	2.4 (0.2, NE)	0.793 (0.248, 2.534)	0.7245

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Cough	13	2 (15.4)	NR (16.5, NE)	17	1 (5.9)	NR (NE, NE)	1.768 (0.075, 41.454)	0.7221
Hiccups	13	2 (15.4)	NR (NE, NE)	17	4 (23.5)	NR (2.4, NE)	0.283 (0.049, 1.624)	0.1387
Pneumonia aspiration	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	21.4 (21.4, NE)	1.000 (0.053, 18.915)	1.0000

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	13	6 (46.2)	6.9 (1.2, NE)	17	7 (41.2)	12.9 (1.2, NE)	0.932 (0.251, 3.464)	0.8956
Alopecia	13	2 (15.4)	NR (3.3, NE)	17	1 (5.9)	NR (NE, NE)	2.631 (0.211, 32.795)	0.4396
Palmar-plantar erythrodysaesthesia syndrome	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.6, NE)	0.000 (0.000, NE)	0.3173
Pruritus	13	3 (23.1)	NR (4.7, NE)	17	1 (5.9)	NR (12.9, NE)	>999.99 (0.000, NE)	0.4190
Rash	13	2 (15.4)	NR (6.9, NE)	17	1 (5.9)	NR (NE, NE)	1.699 (0.135, 21.378)	0.6790

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v24.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Vascular disorders	13	2 (15.4)	NR (5.4, NE)	17	4 (23.5)	NR (3.5, NE)	0.181 (0.019, 1.744)	0.1049
Flushing	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0673

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	2 (15.4)	NR (1.6, NE)	17	4 (23.5)	NR (4.0, NE)	0.819 (0.123, 5.460)	0.8364
Anaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.0, NE)	0.000 (0.000, NE)	0.0859
Leukopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Lymphopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Neutropenia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (5.0, NE)	0.000 (0.000, NE)	0.2008
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Eye disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859
Cataract	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	5 (29.4)	NR (1.1, NE)	0.424 (0.042, 4.291)	0.4580
Acquired soft palate fissure	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Diarrhoea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.630 (0.049, 8.140)	0.7214

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	13	2 (15.4)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0325
Asthenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Fatigue	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3173

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	13	2 (15.4)	NR (5.0, NE)	17	1 (5.9)	NR (NE, NE)	7.027 (0.614, 80.430)	0.0717
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Investigations	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.376 (0.084, 1.686)	0.1984
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4795
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	4 (23.5)	NR (2.1, NE)	0.844 (0.197, 3.605)	0.8183
White blood cell count decreased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.4, NE)	0.000 (0.000, NE)	0.1499
Metabolism and nutrition disorders	13	3 (23.1)	NR (1.8, NE)	17	5 (29.4)	11.2 (4.1, NE)	0.737 (0.126, 4.302)	0.7342
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	3.162 (0.184, 54.388)	0.4054
Hyperkalaemia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Hypoglycaemia	13	1 (7.7)	NR (17.2, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.1, NE)	0.000 (0.000, NE)	0.1439
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (11.2, NE)	0.000 (0.000, NE)	0.4795
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Skin and subcutaneous tissue disorders	13	2 (15.4)	41.2 (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Rash	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Skin toxicity	13	1 (7.7)	41.2 (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (20.5, NE)	0.821 (0.062, 10.940)	0.8814
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Nausea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Asthenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Infections and infestations	13	3 (23.1)	NR (1.5, NE)	17	1 (5.9)	NR (NE, NE)	7.889 (0.745, 83.509)	0.0530
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Pulmonary tuberculosis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Metabolism and nutrition disorders	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	1.000 (0.081, 12.270)	1.0000
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	0.000 (0.000, NE)	0.2253
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Nervous system disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Presyncope	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Patients with at Least One TEAE Leading to Any Treatment Discontinuation	2 (15.4)	6 (35.3)
General disorders and administration site conditions	1 (7.7)	0 (0.0)
Asthenia	1 (7.7)	0 (0.0)
Metabolism and nutrition disorders	1 (7.7)	0 (0.0)
Decreased appetite	1 (7.7)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (7.7)	0 (0.0)
Rash	1 (7.7)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	1 (5.9)
Acquired soft palate fissure	0 (0.0)	1 (5.9)

Source: ADSL, ADAE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Percentages were based on N.

Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.

Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.

Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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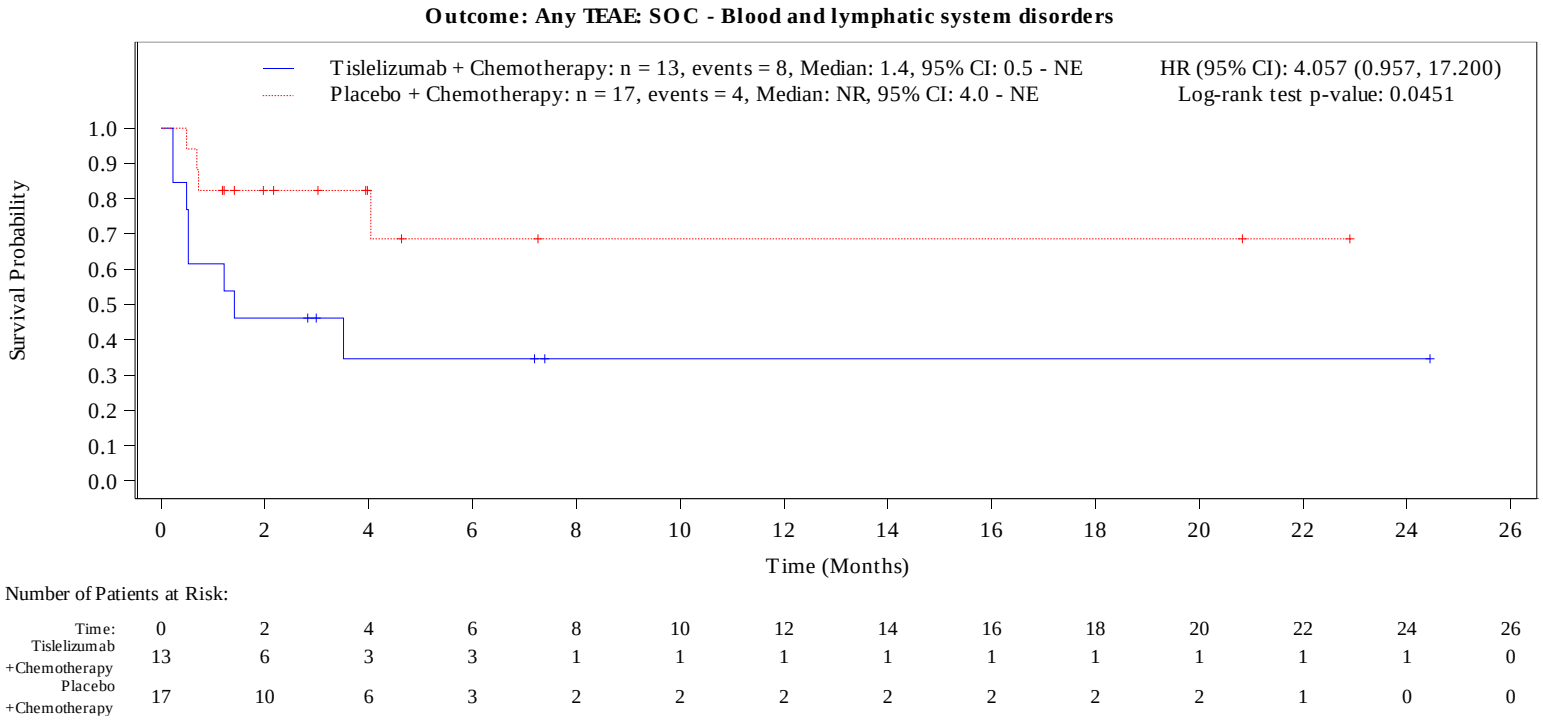
Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Infections and infestations	0 (0.0)	1 (5.9)
Pneumonia	0 (0.0)	1 (5.9)
Nervous system disorders	0 (0.0)	1 (5.9)
Peripheral sensory neuropathy	0 (0.0)	1 (5.9)
Renal and urinary disorders	0 (0.0)	3 (17.6)
Chronic kidney disease	0 (0.0)	1 (5.9)
Renal impairment	0 (0.0)	2 (11.8)

Source: ADSL, ADAE. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.
Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-socpt.sas 21OCT2024 08:37 t-14-3-1-5-1-socpt-dis-pop1-3y.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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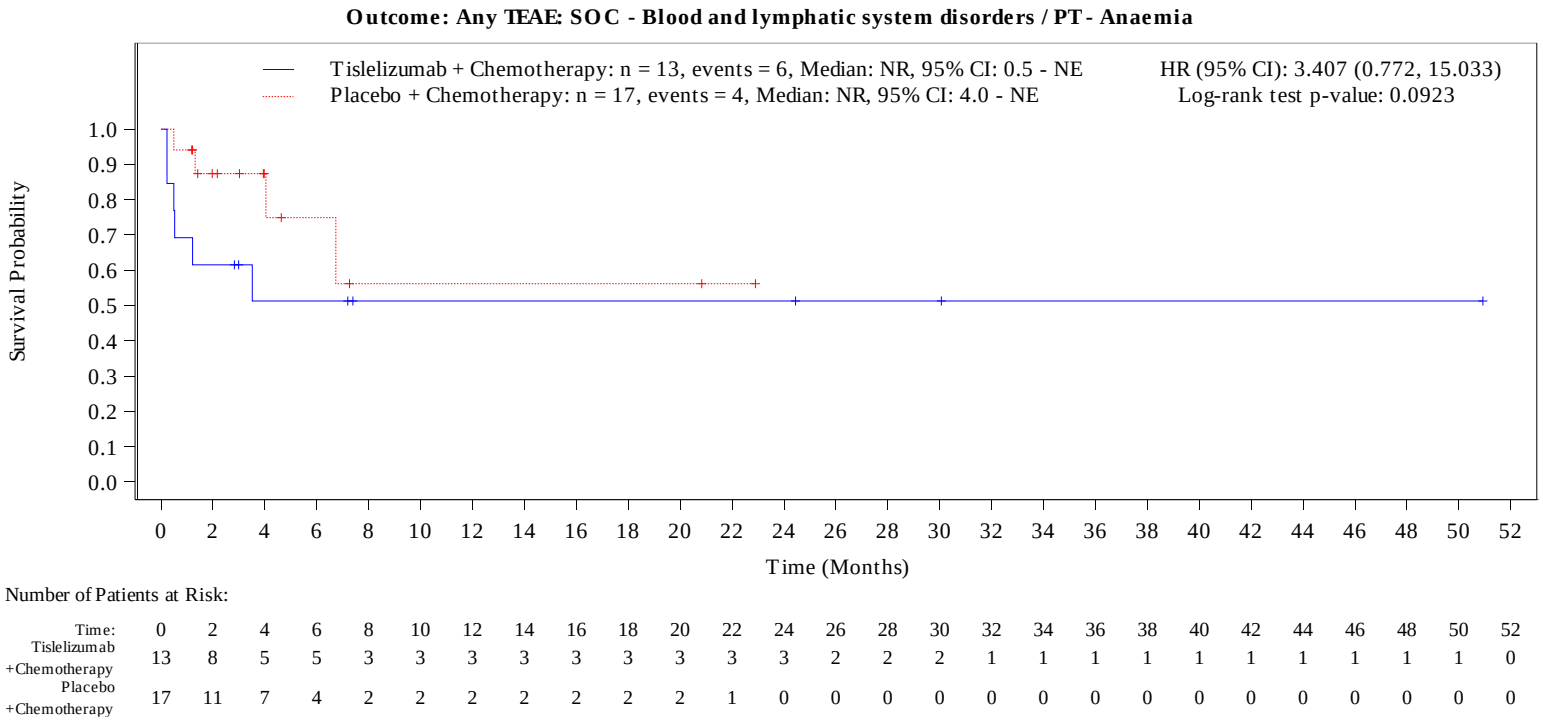
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	8	5	5	3	3	3	3	3	3	3	3	3	2	2	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	7	4	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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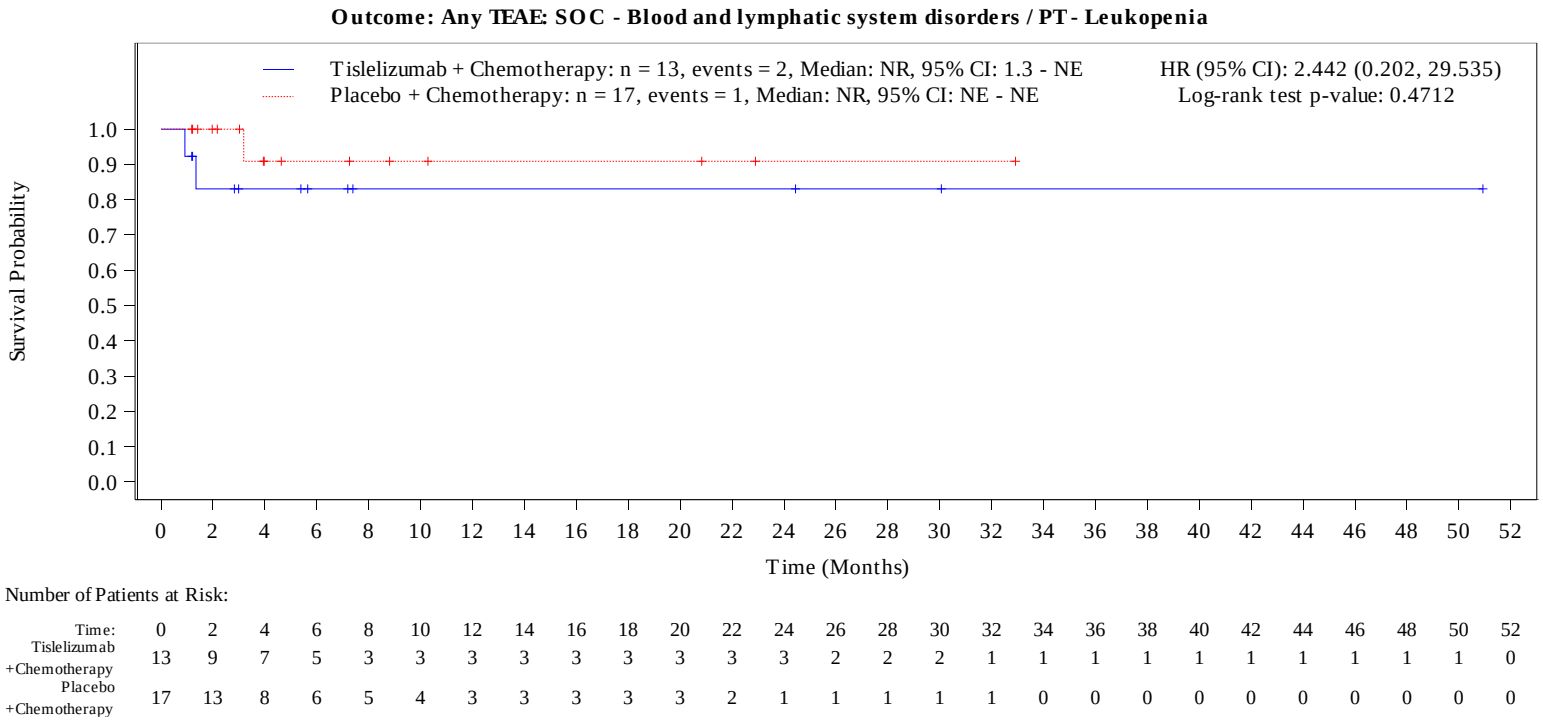
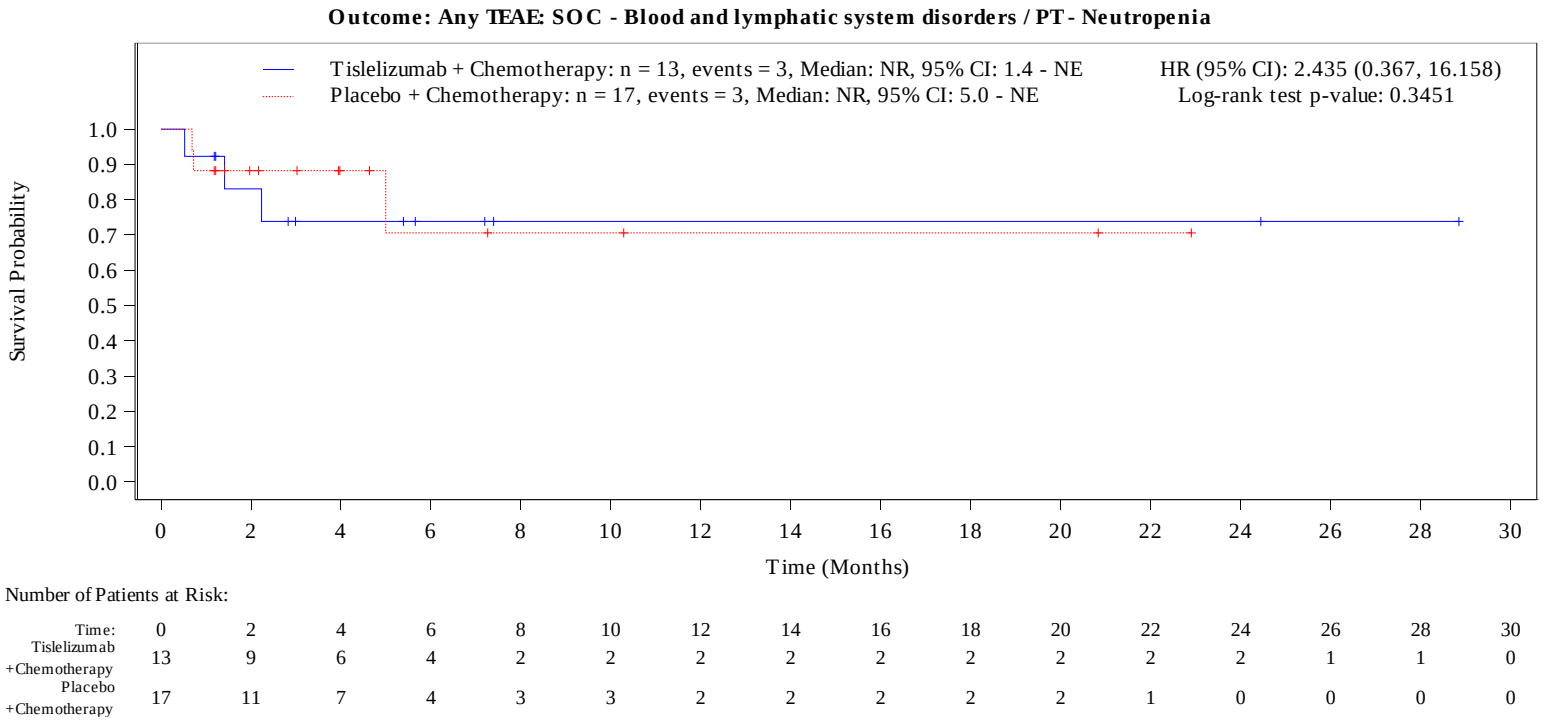
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-2-km-aesocpt-teae-pop1-3y.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab +Chemotherapy	13	9	6	4	2	2	2	2	2	2	2	2	2	1	1	0
Placebo +Chemotherapy	17	11	7	4	3	3	2	2	2	2	2	1	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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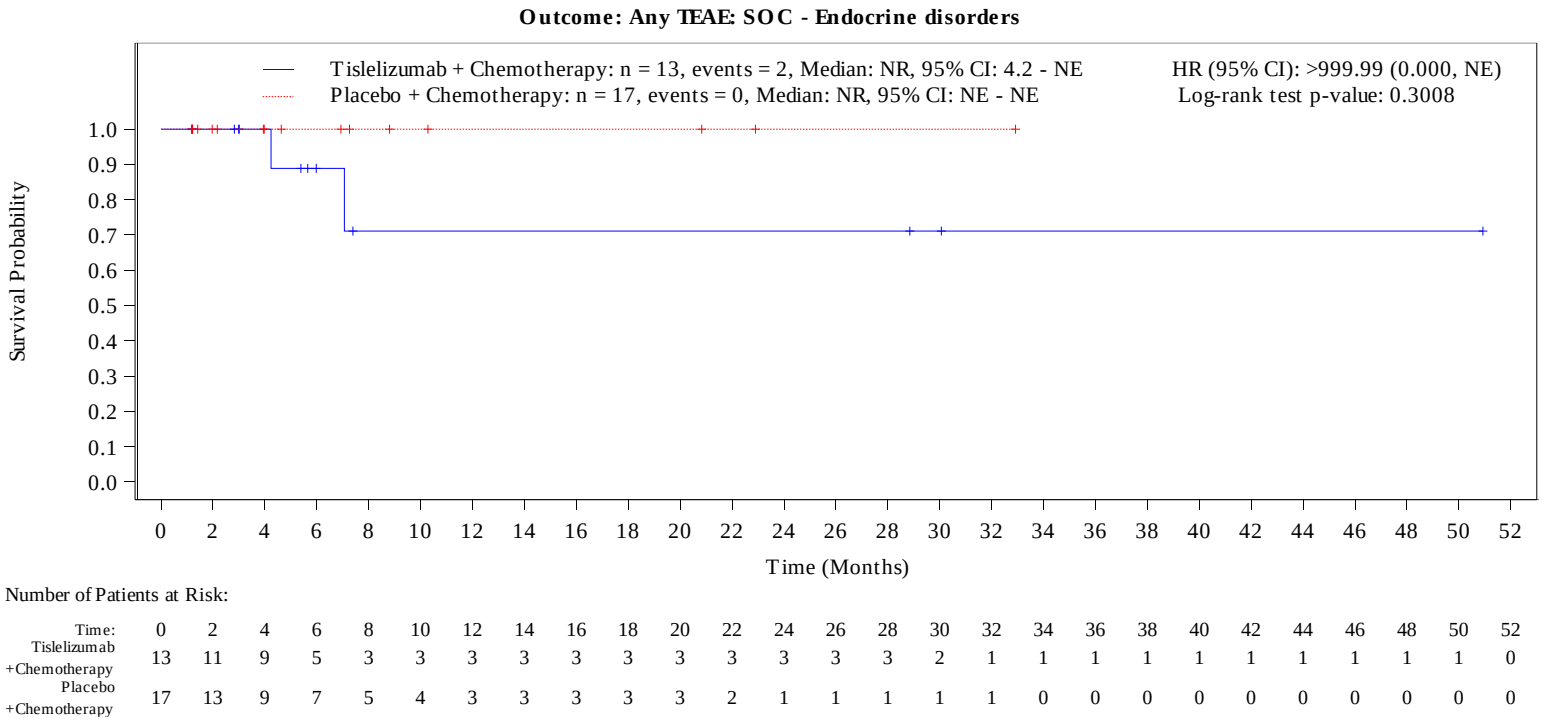
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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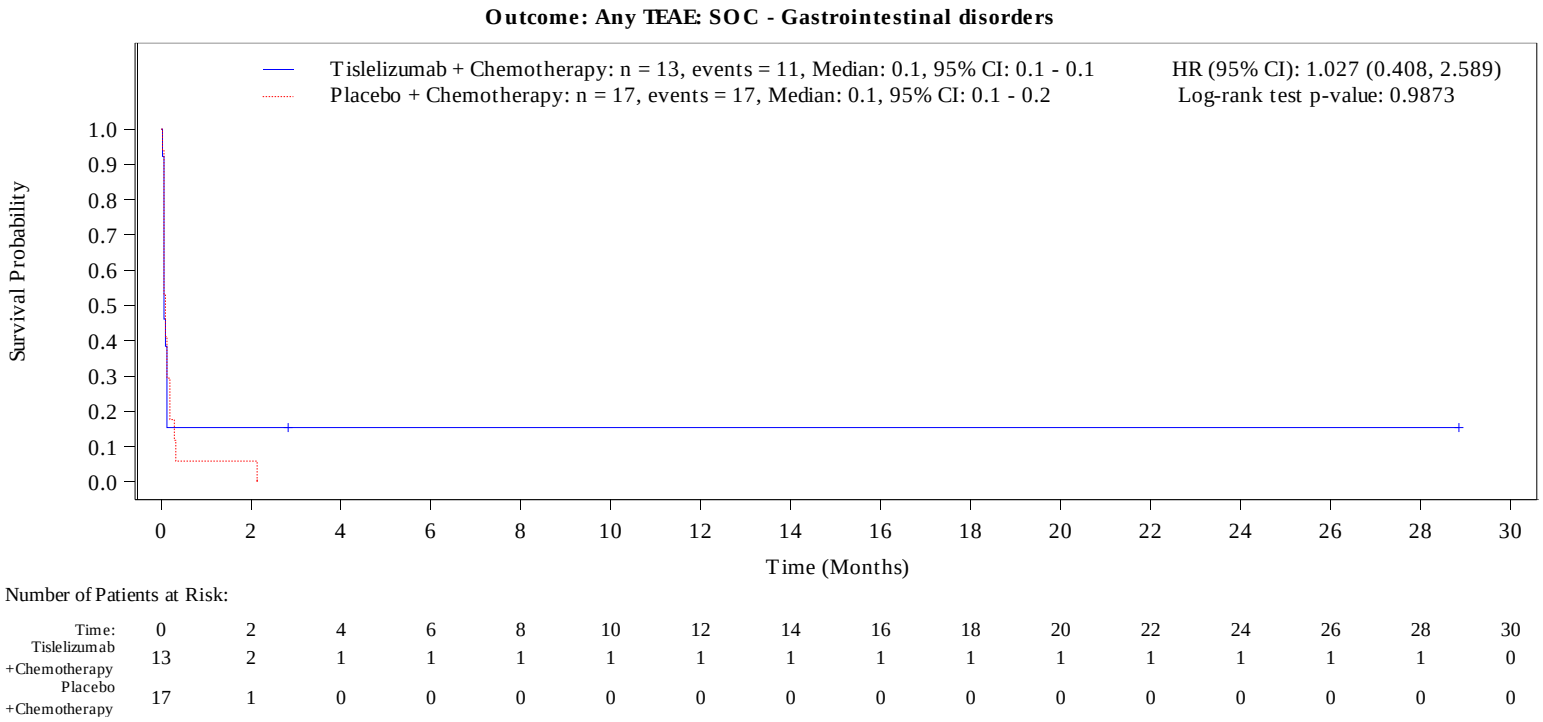

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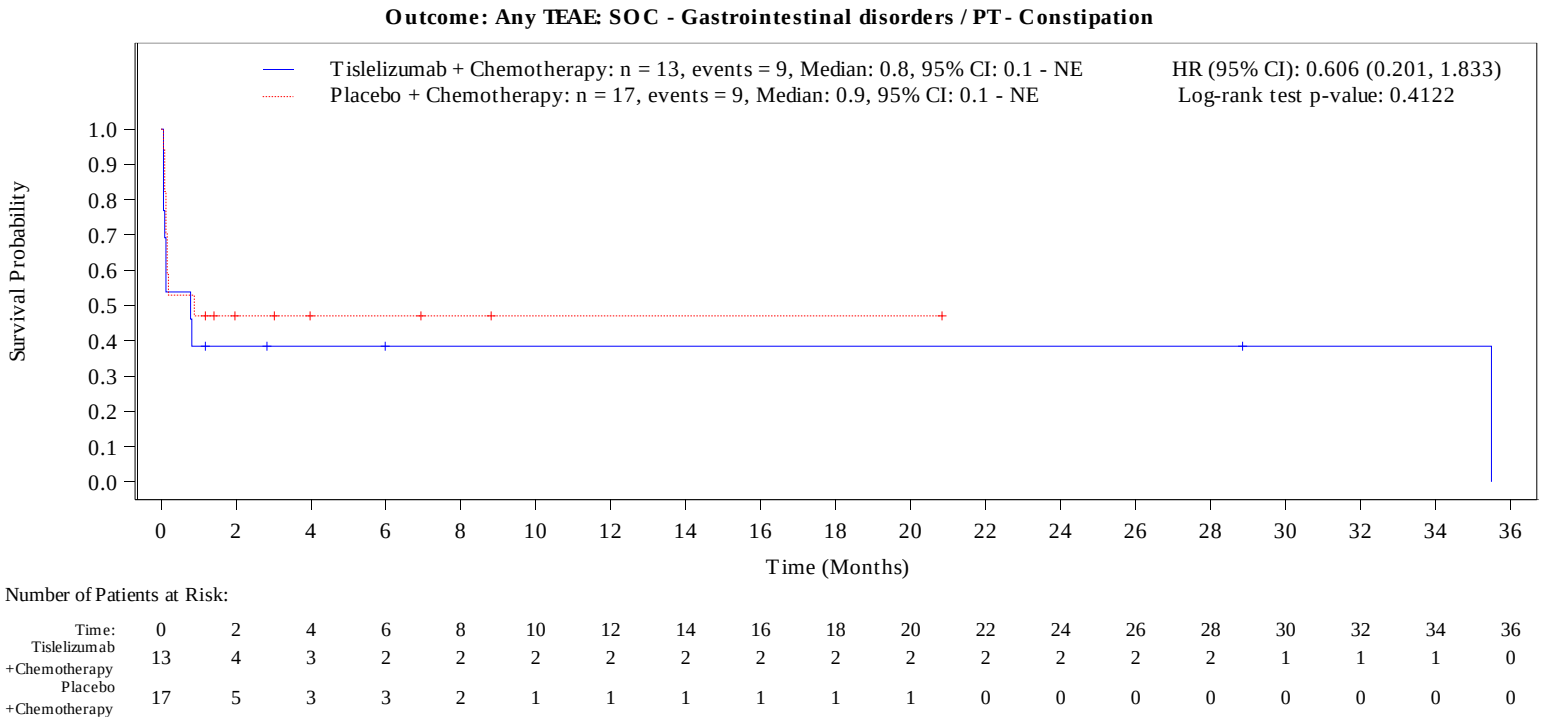

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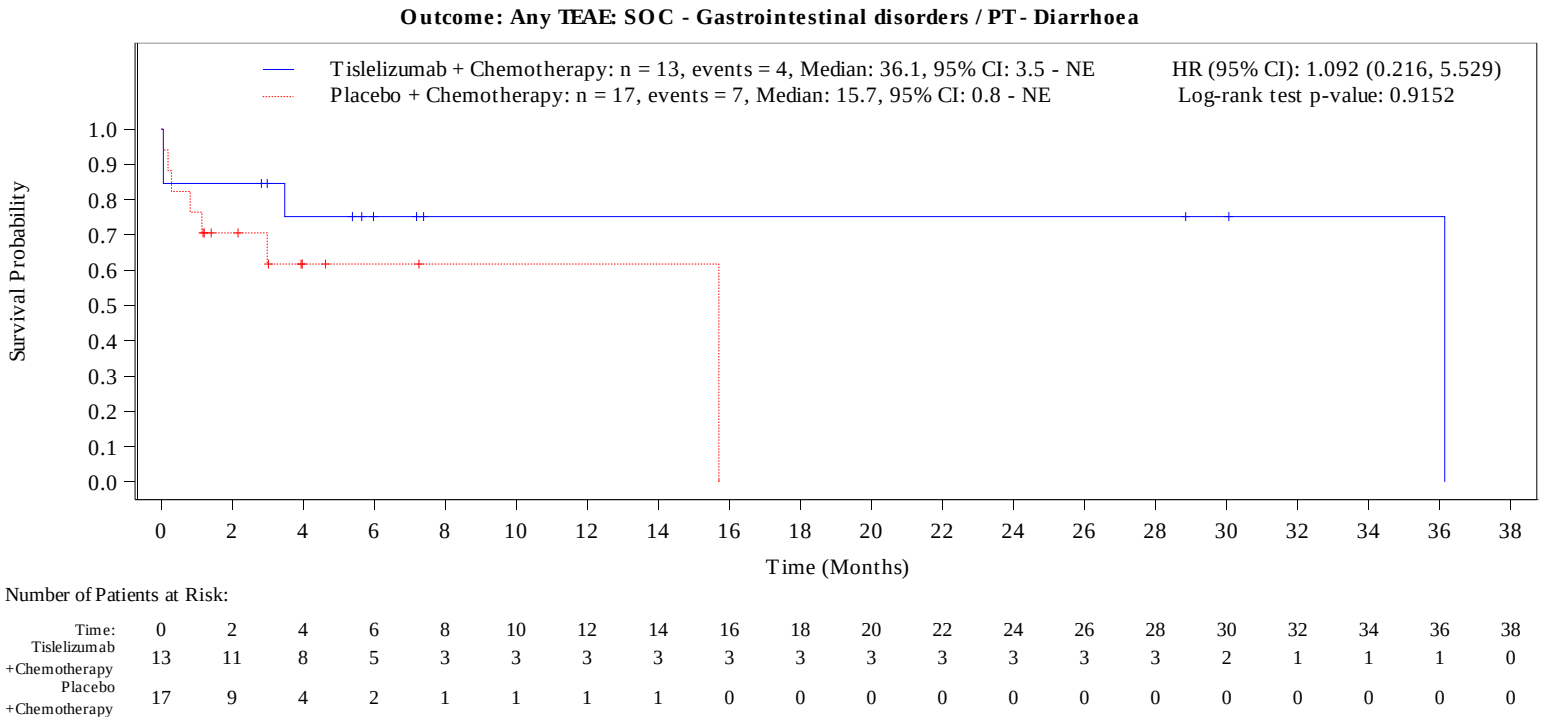

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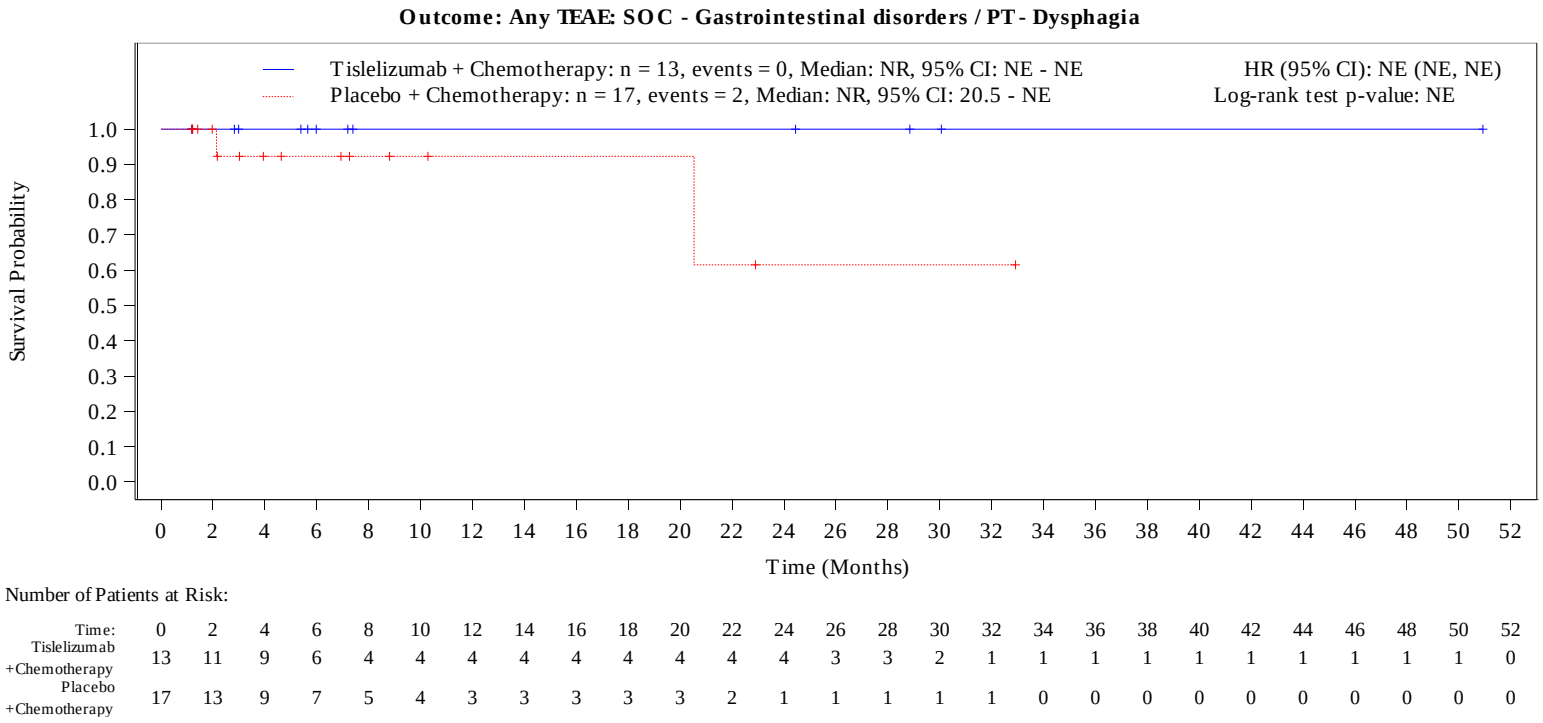
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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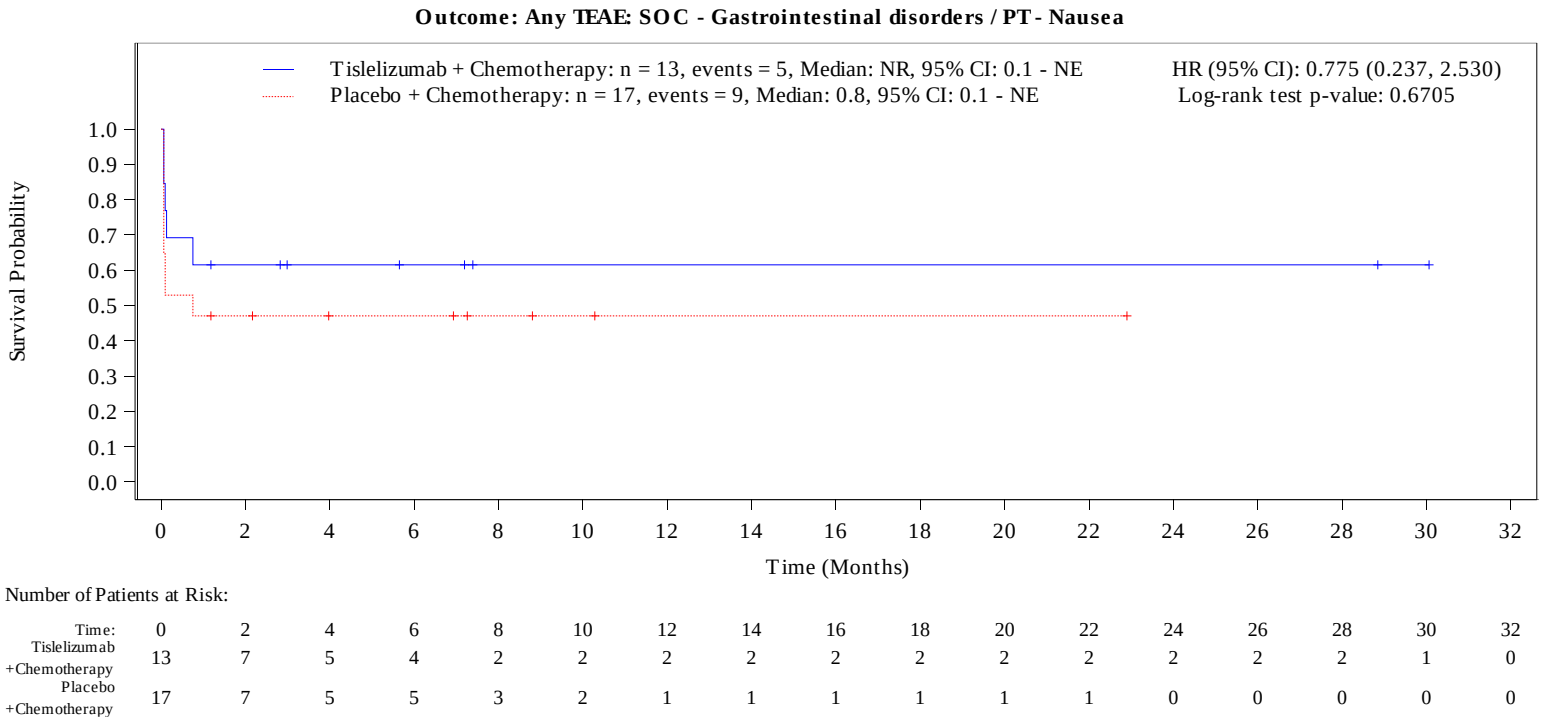

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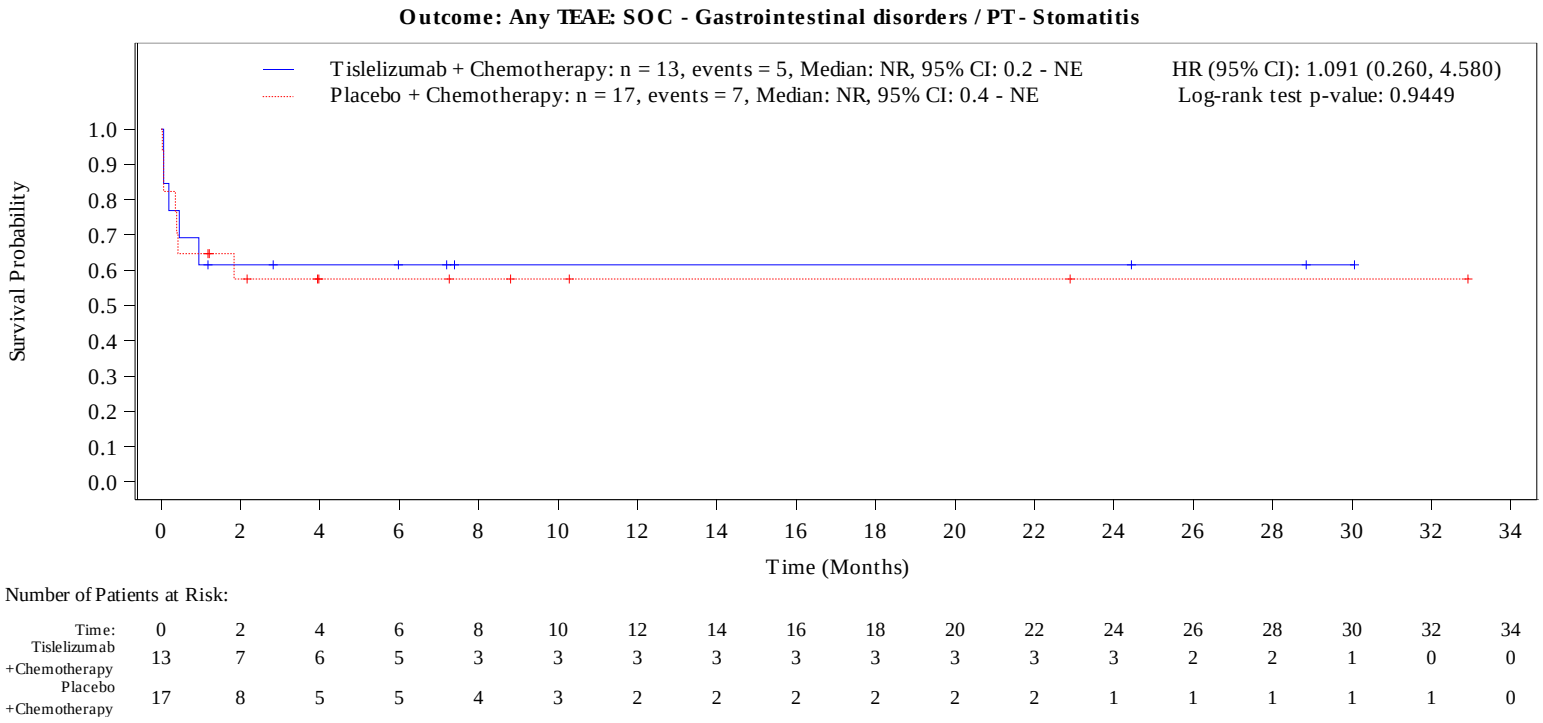

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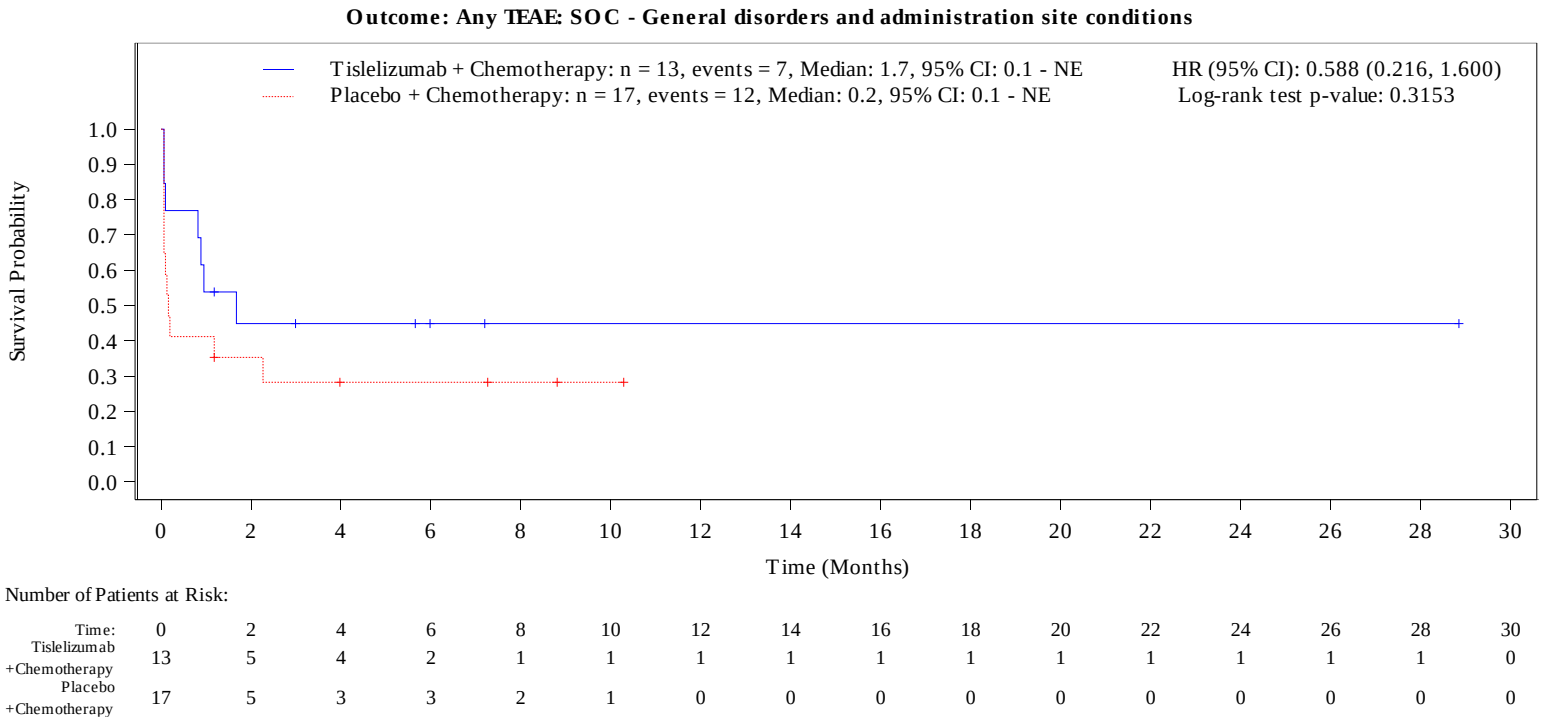

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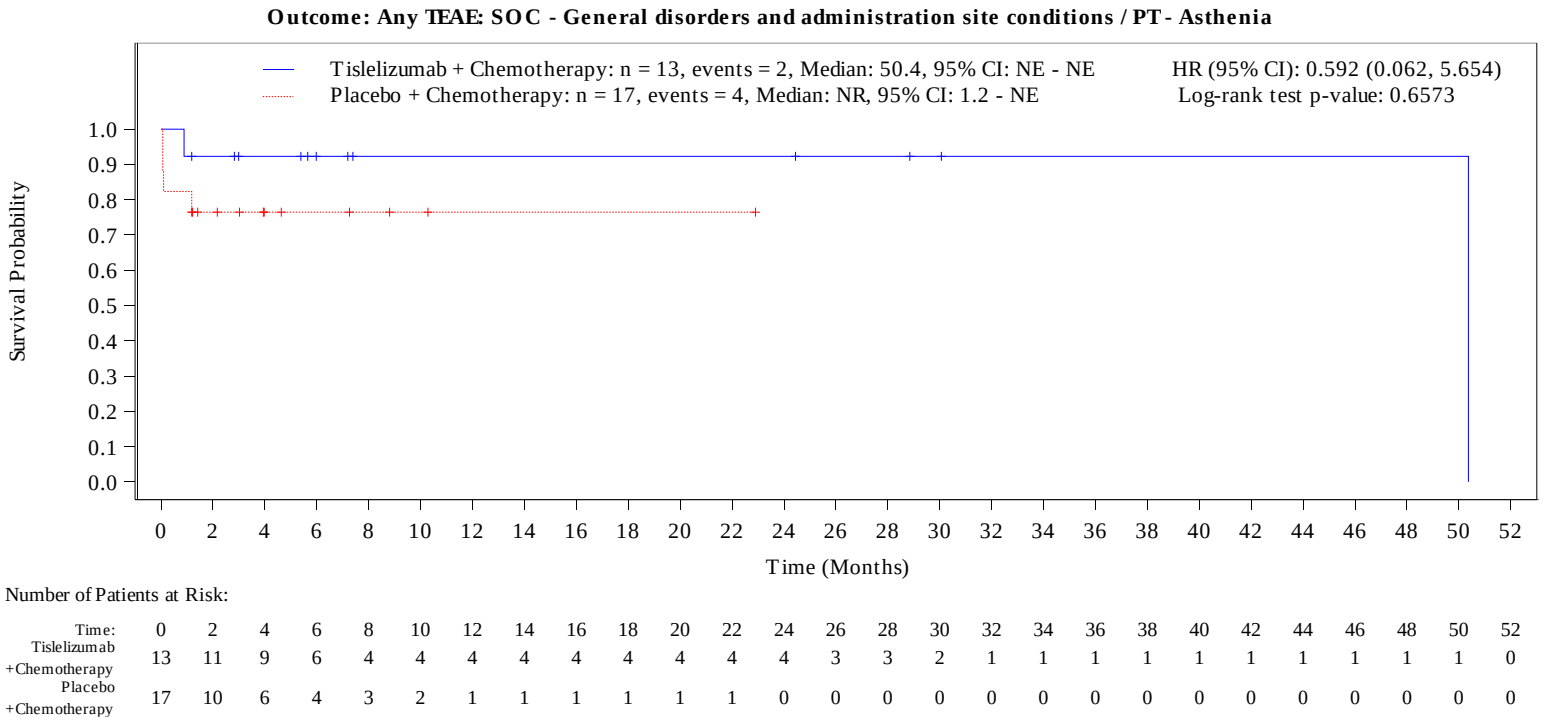

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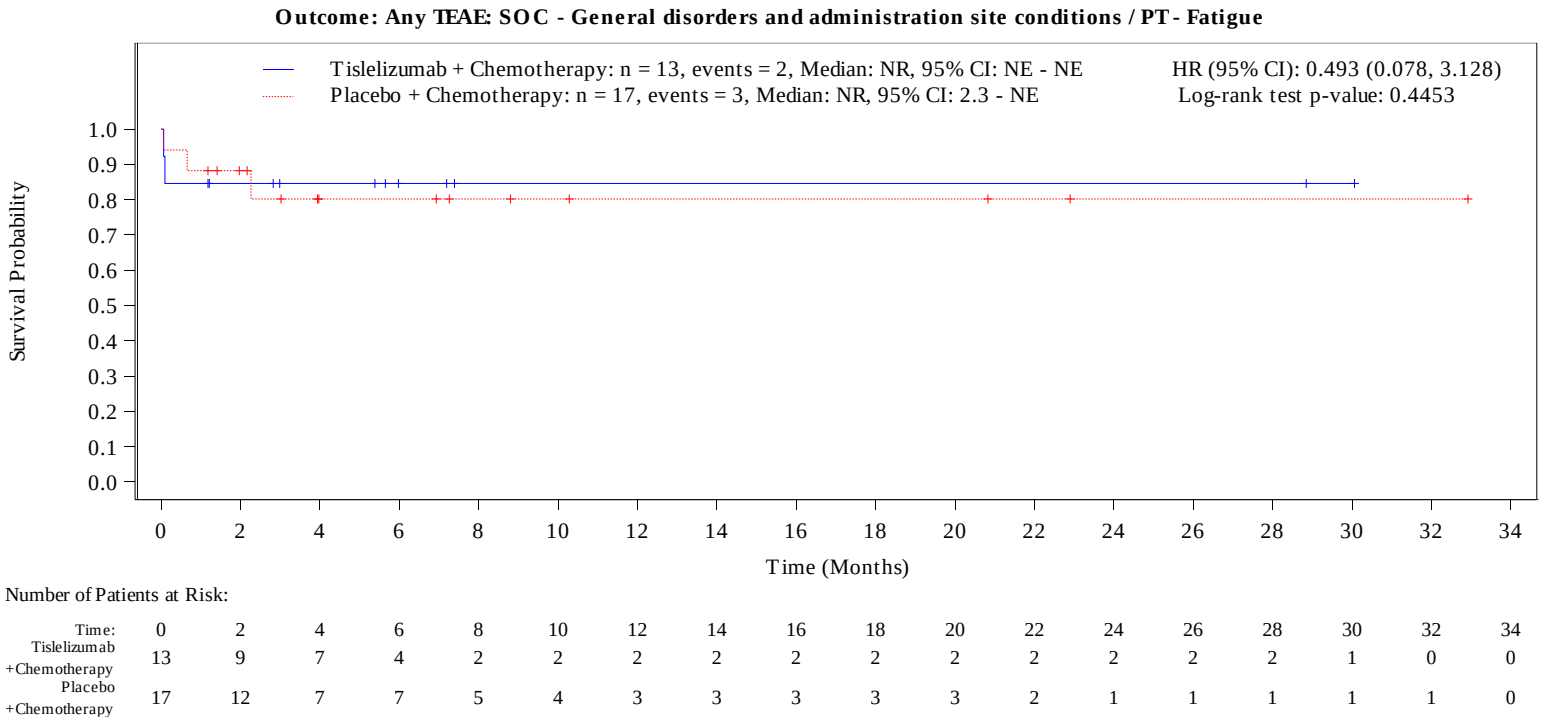

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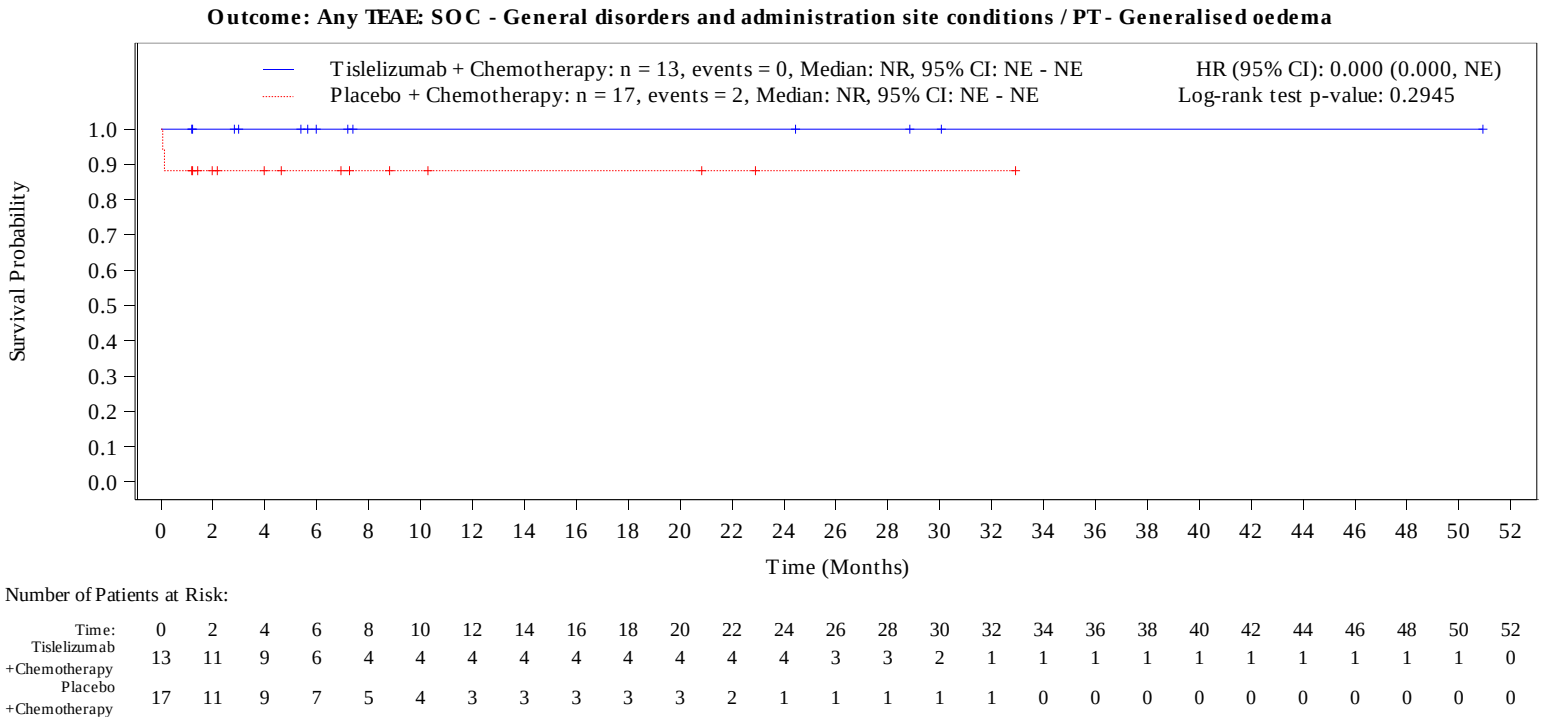

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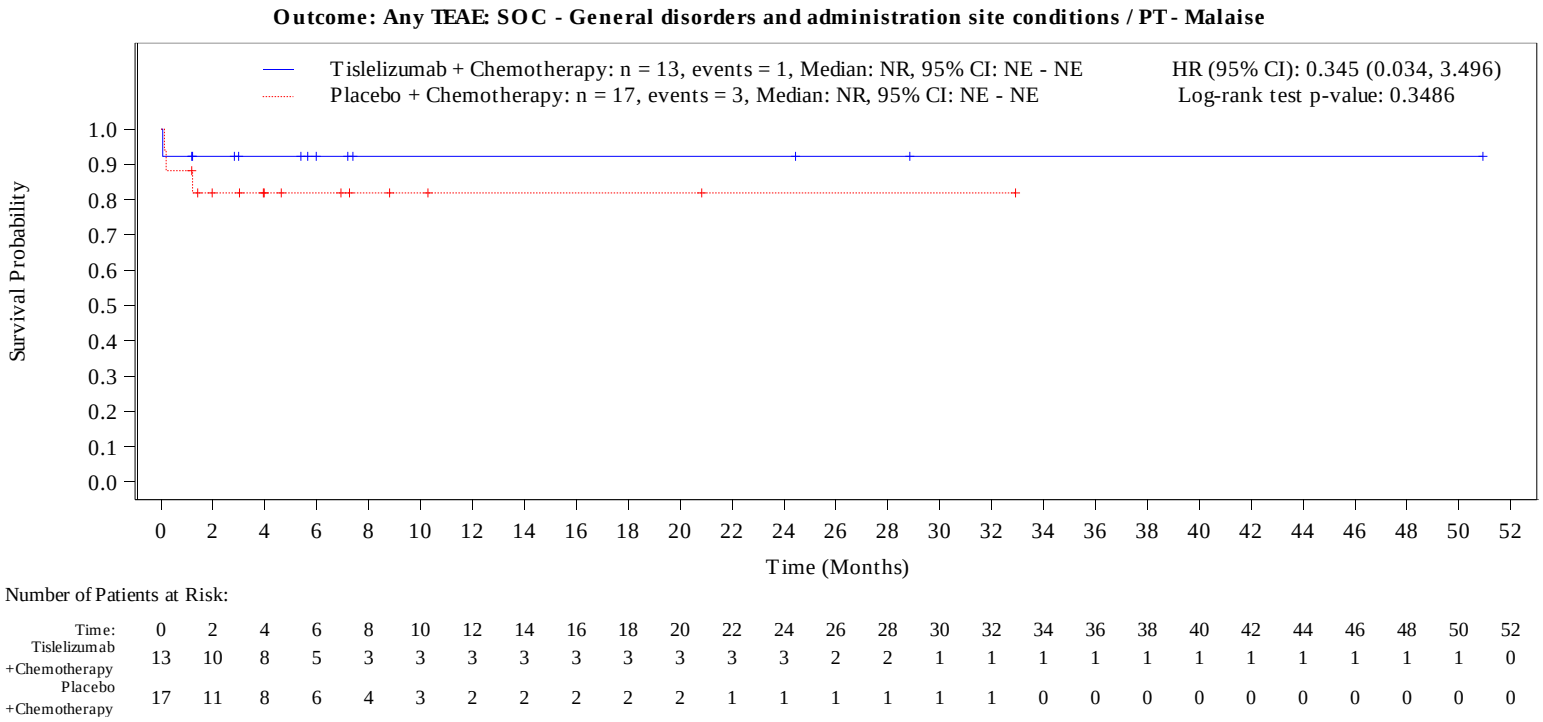

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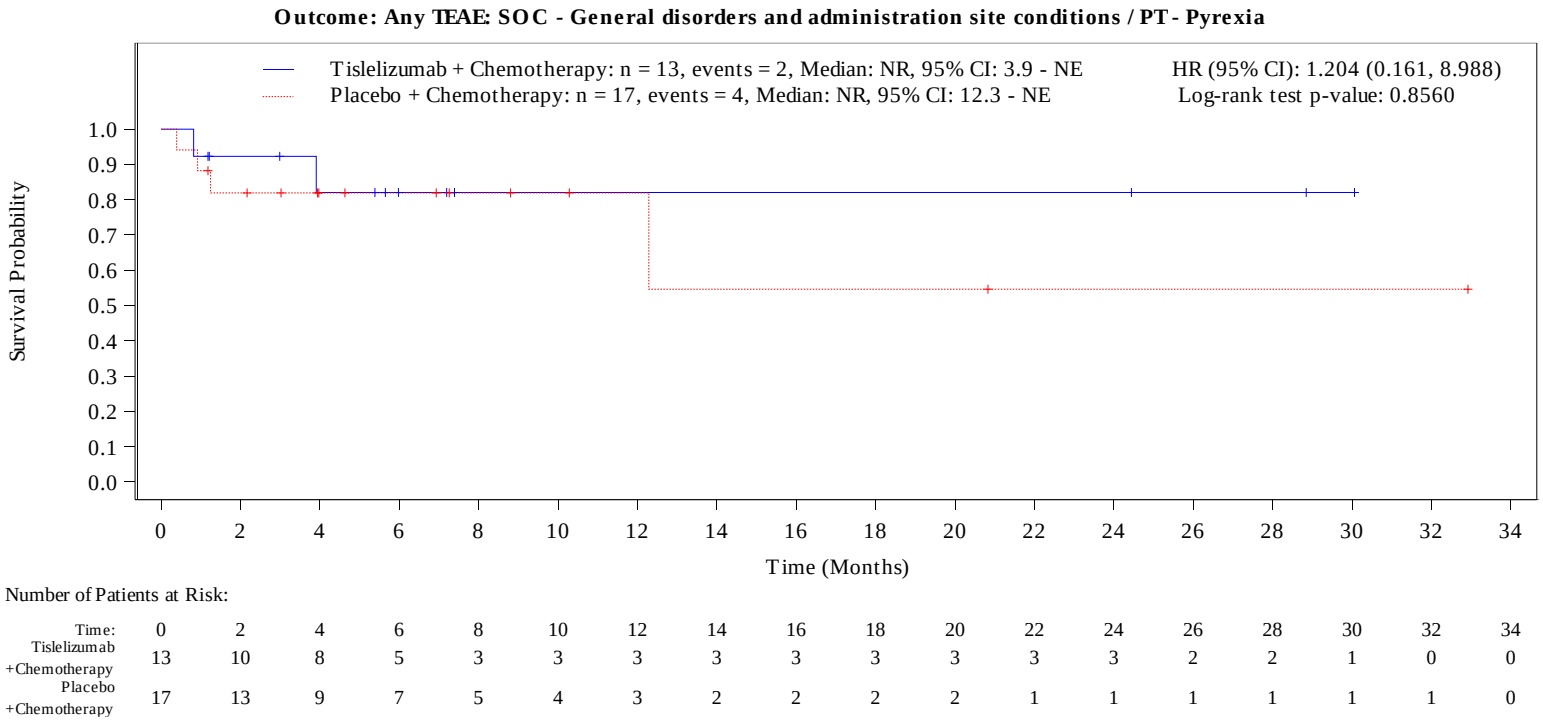

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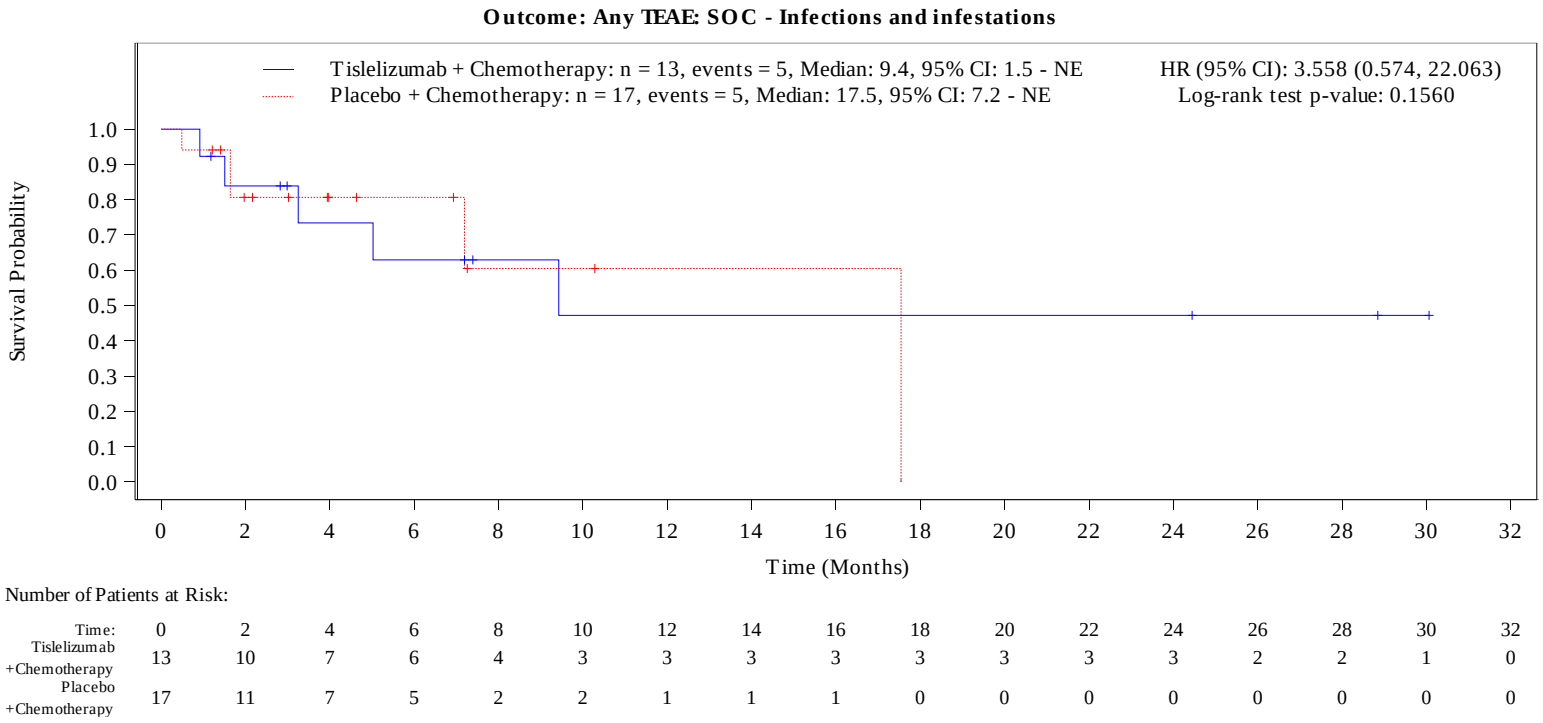

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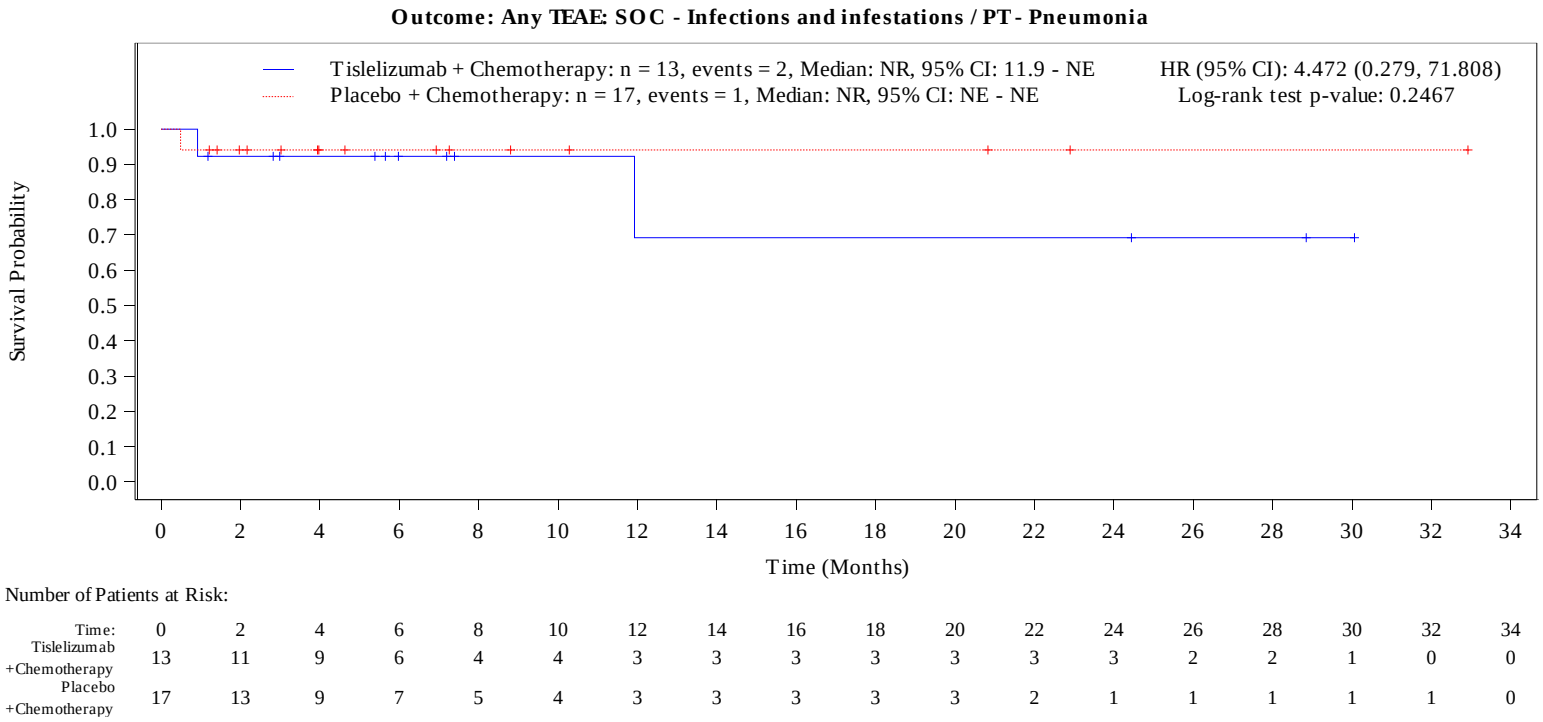

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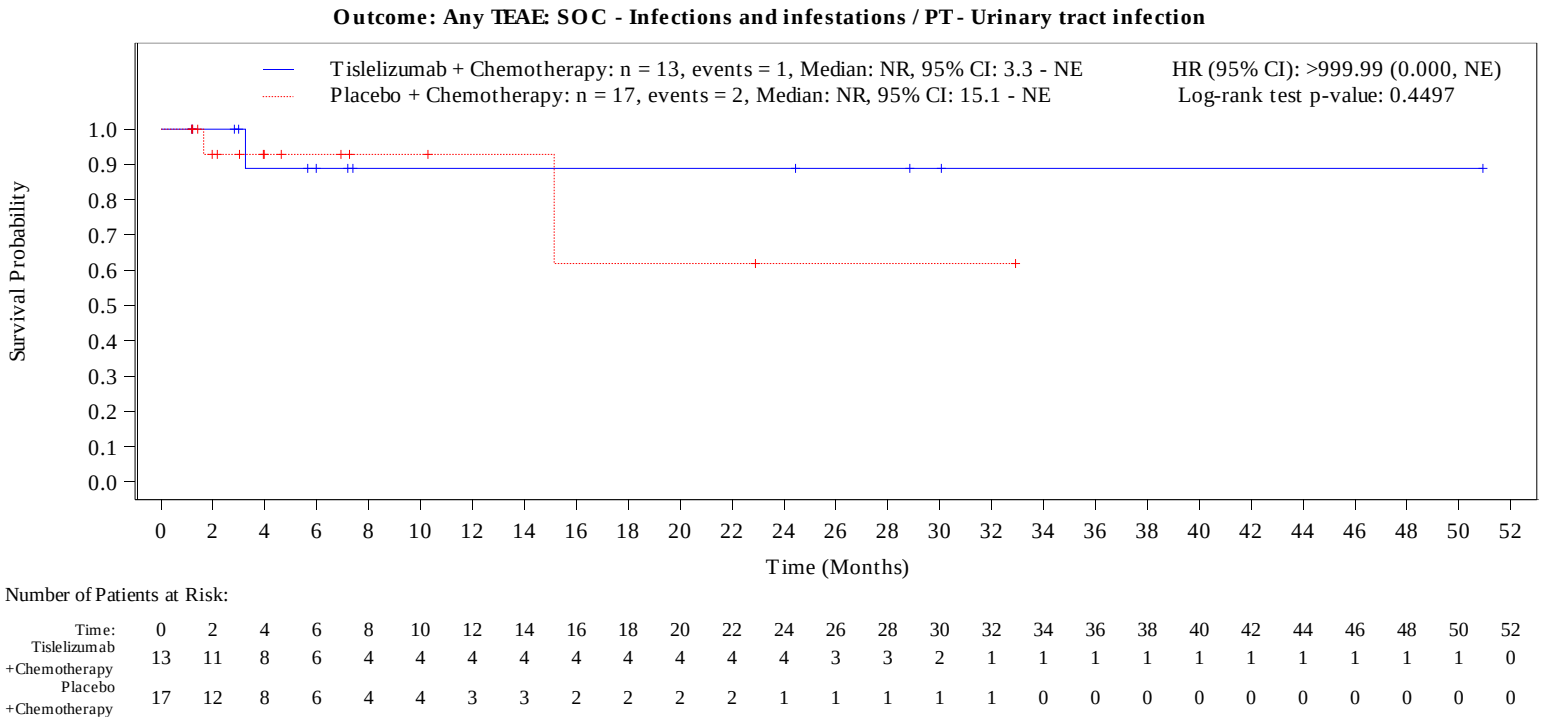

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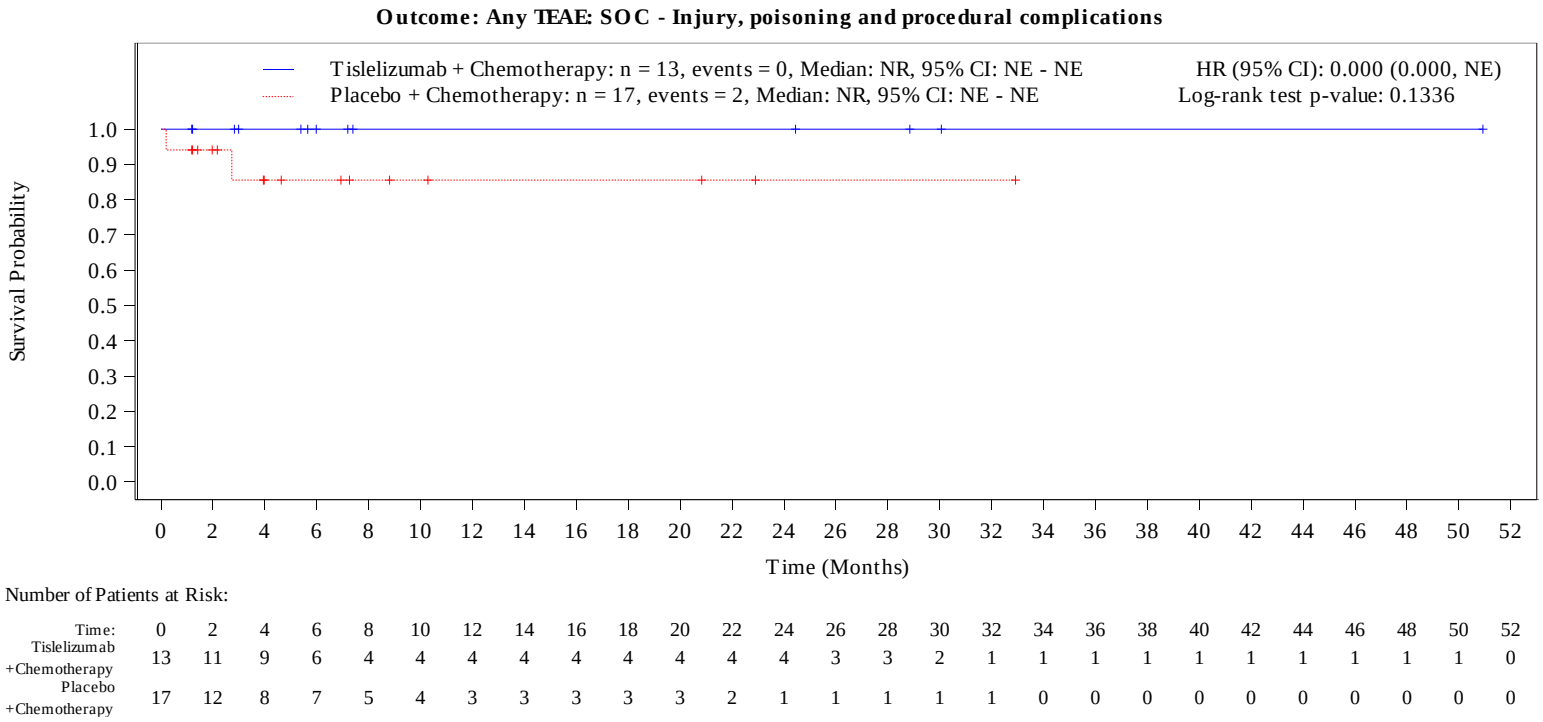

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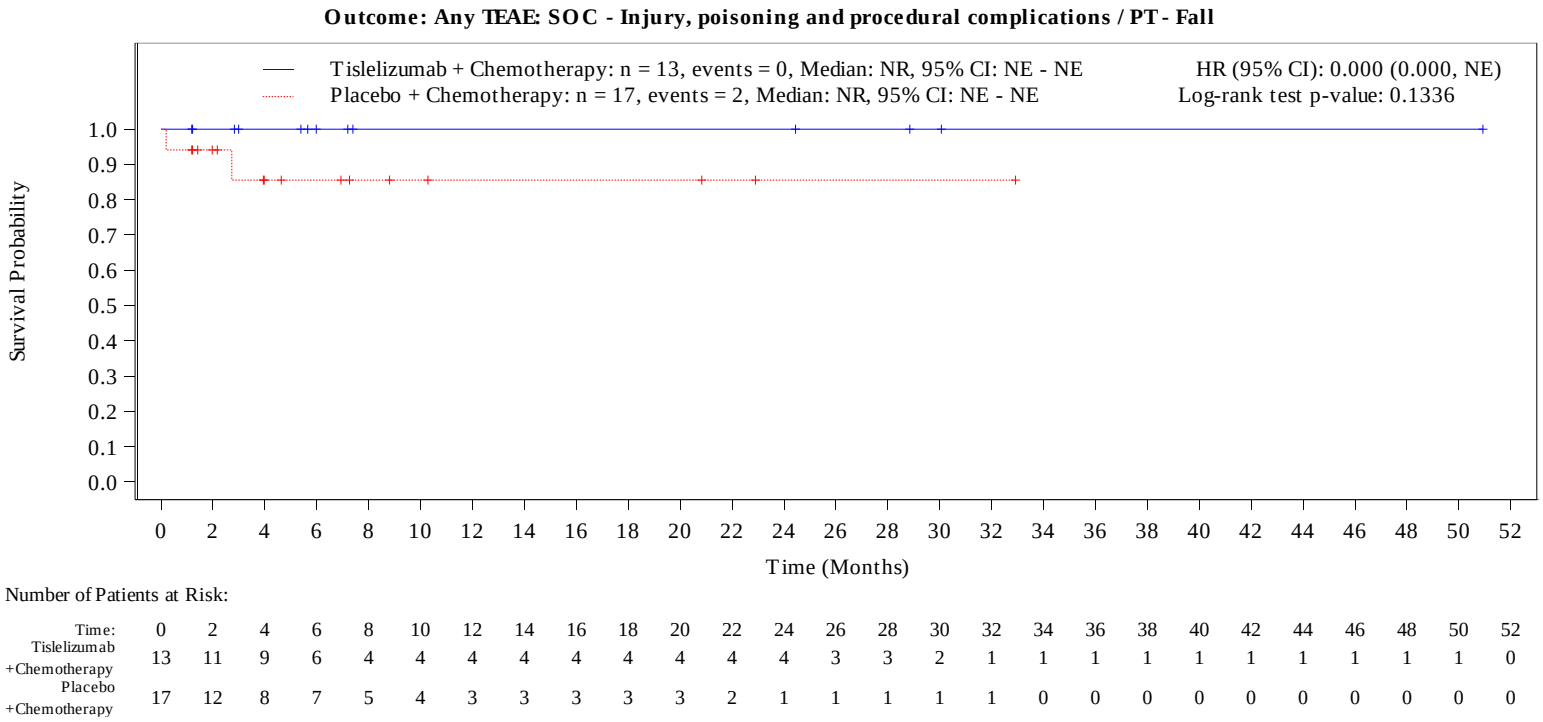

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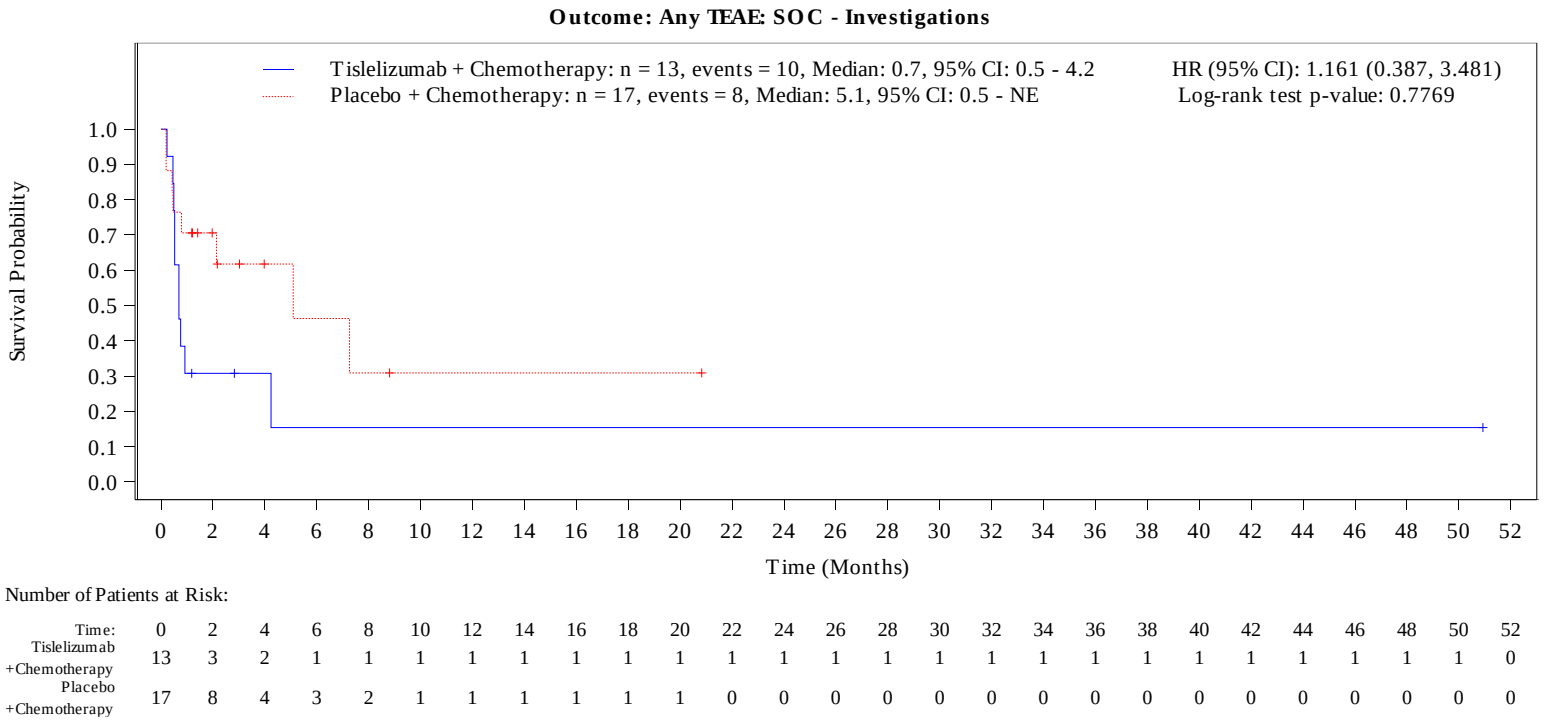

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	8	4	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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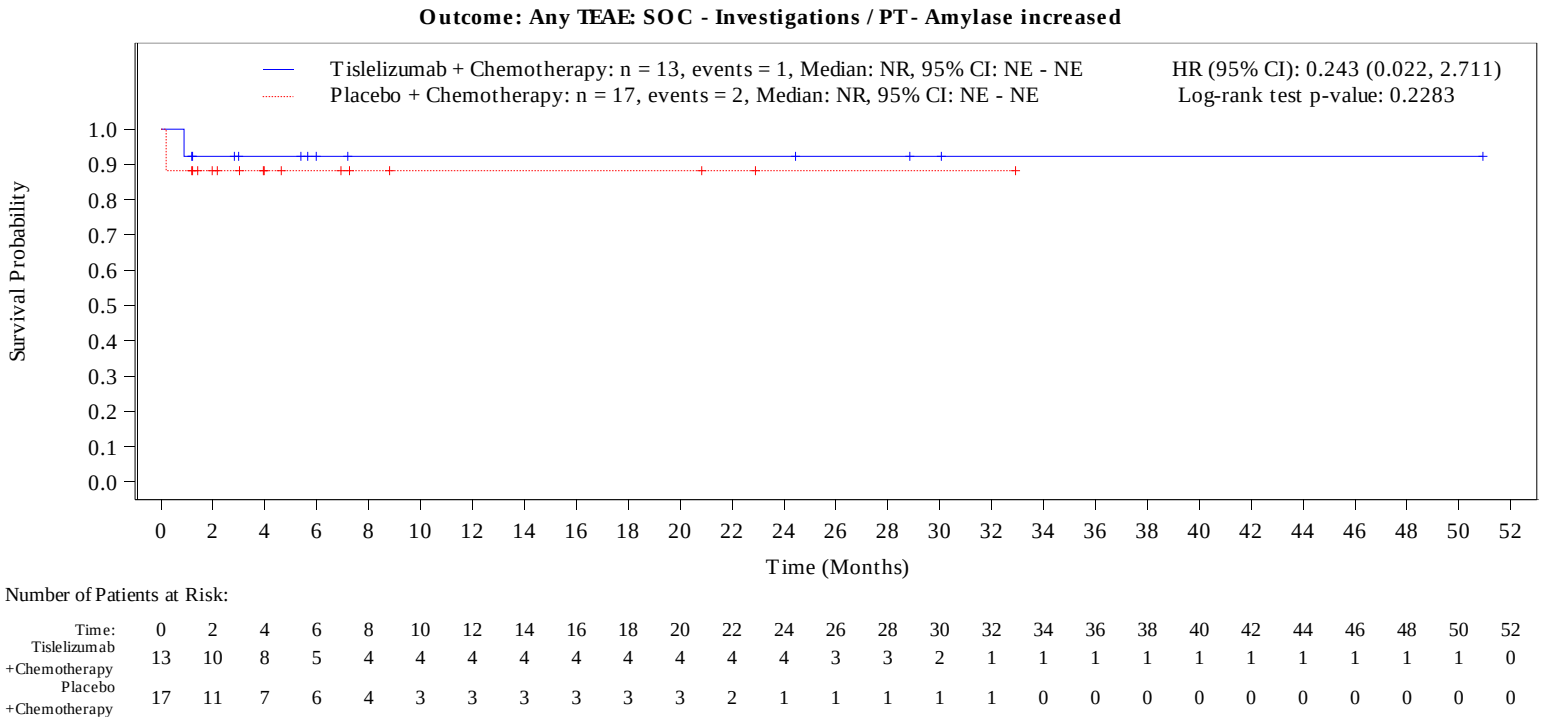
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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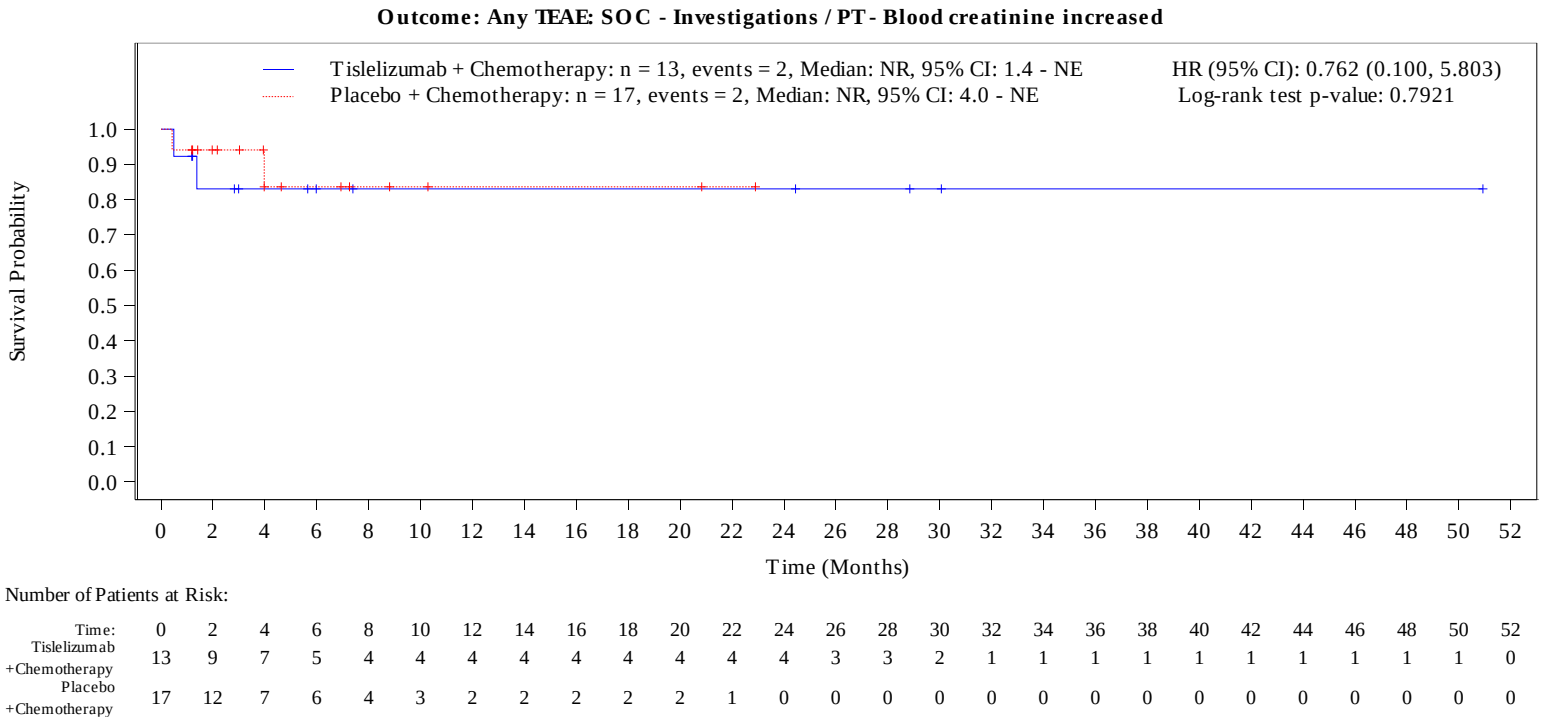

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	9	7	5	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	7	6	4	3	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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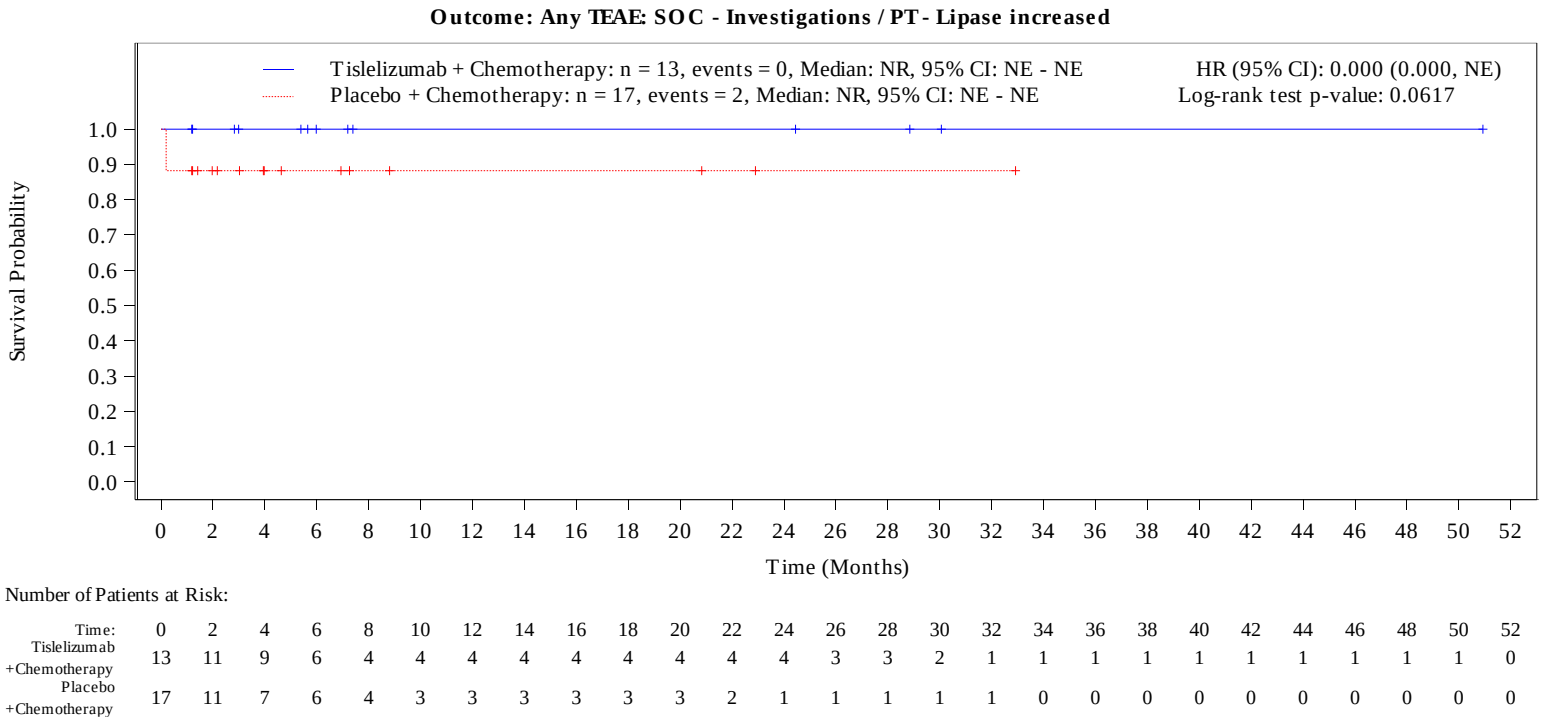

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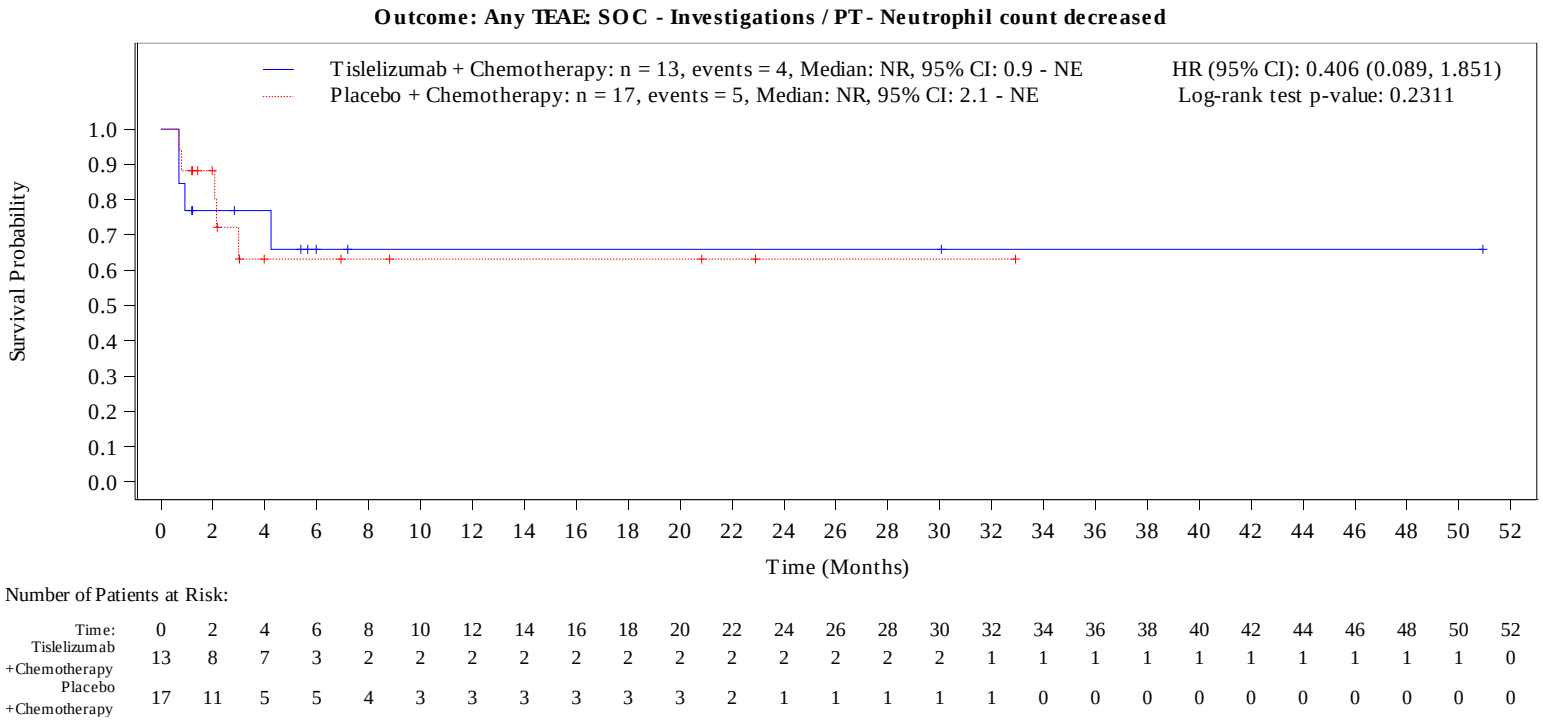

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	8	7	3	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	5	5	4	3	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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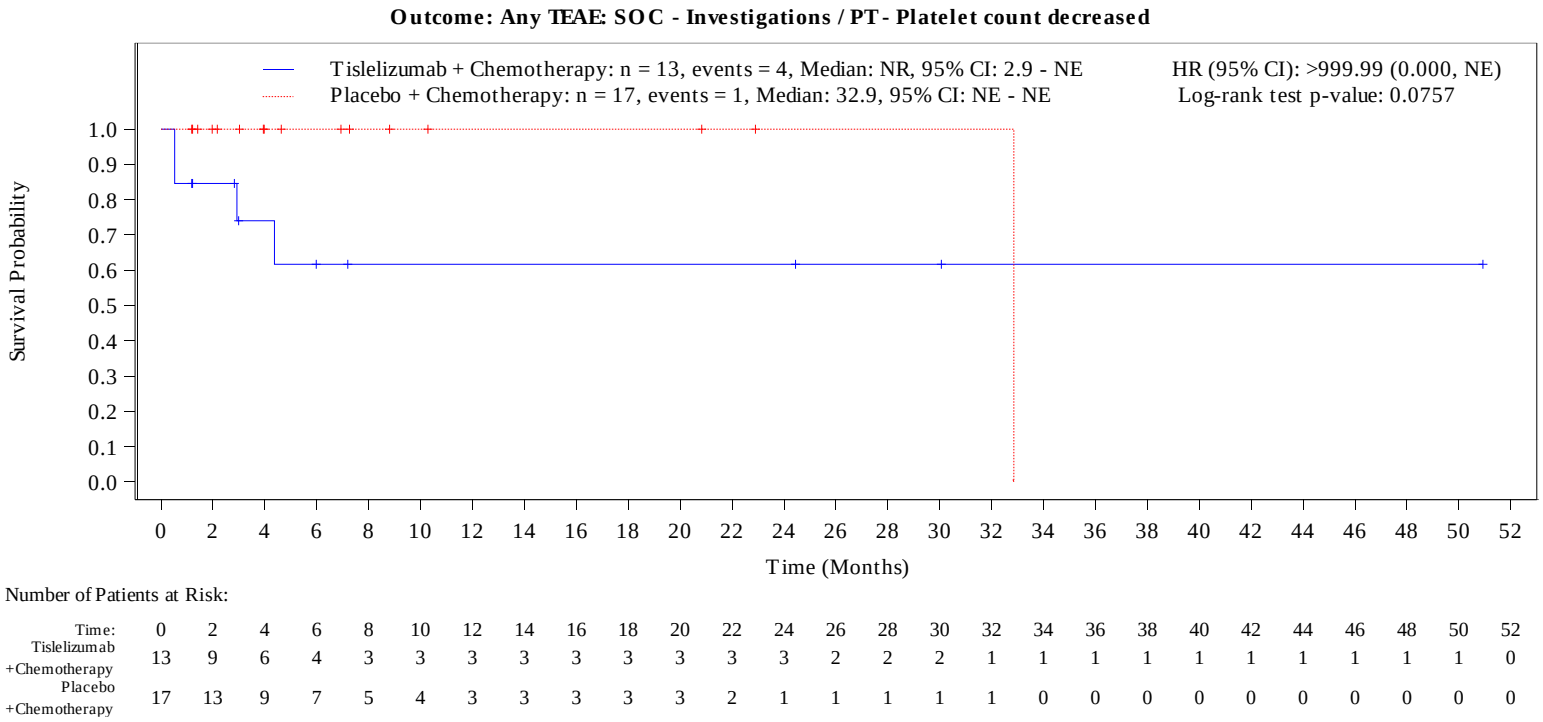

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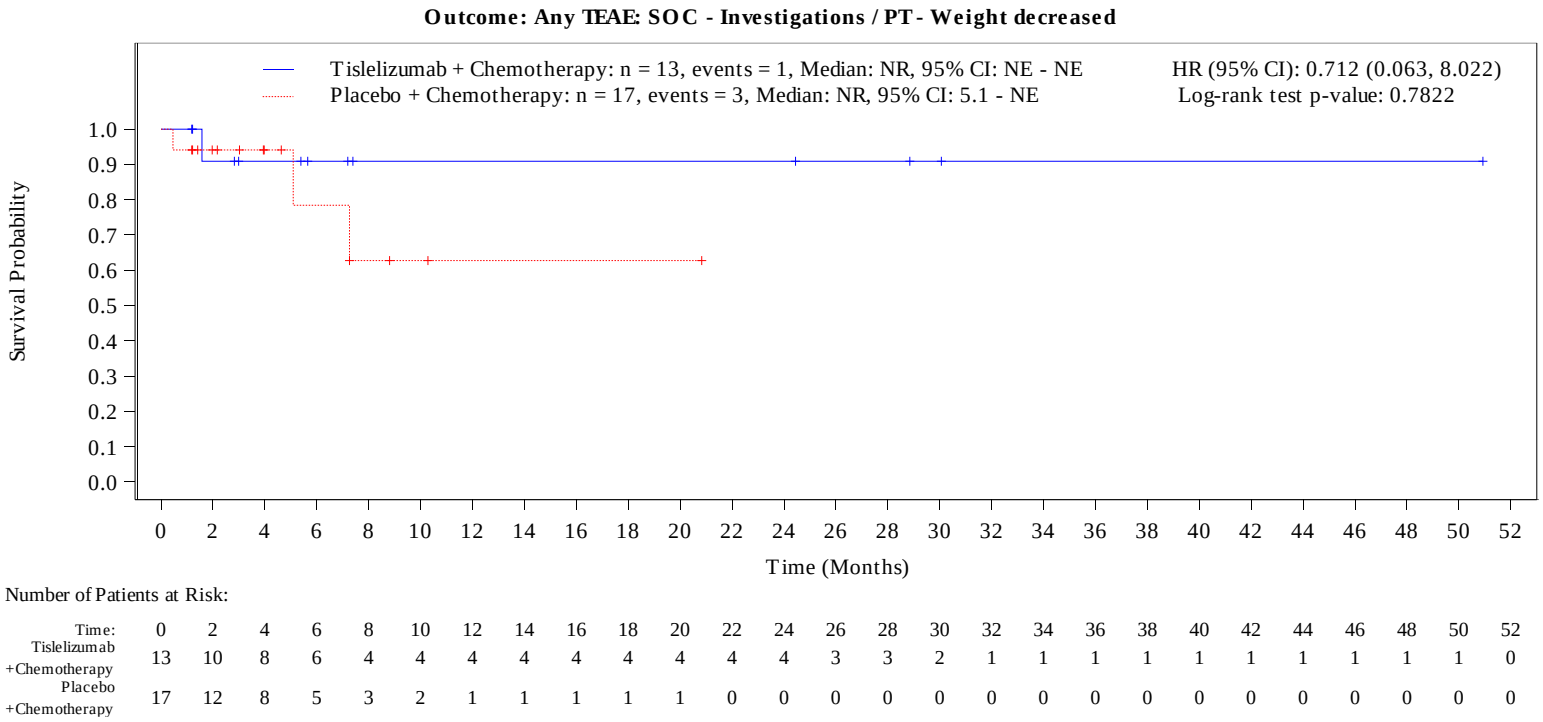

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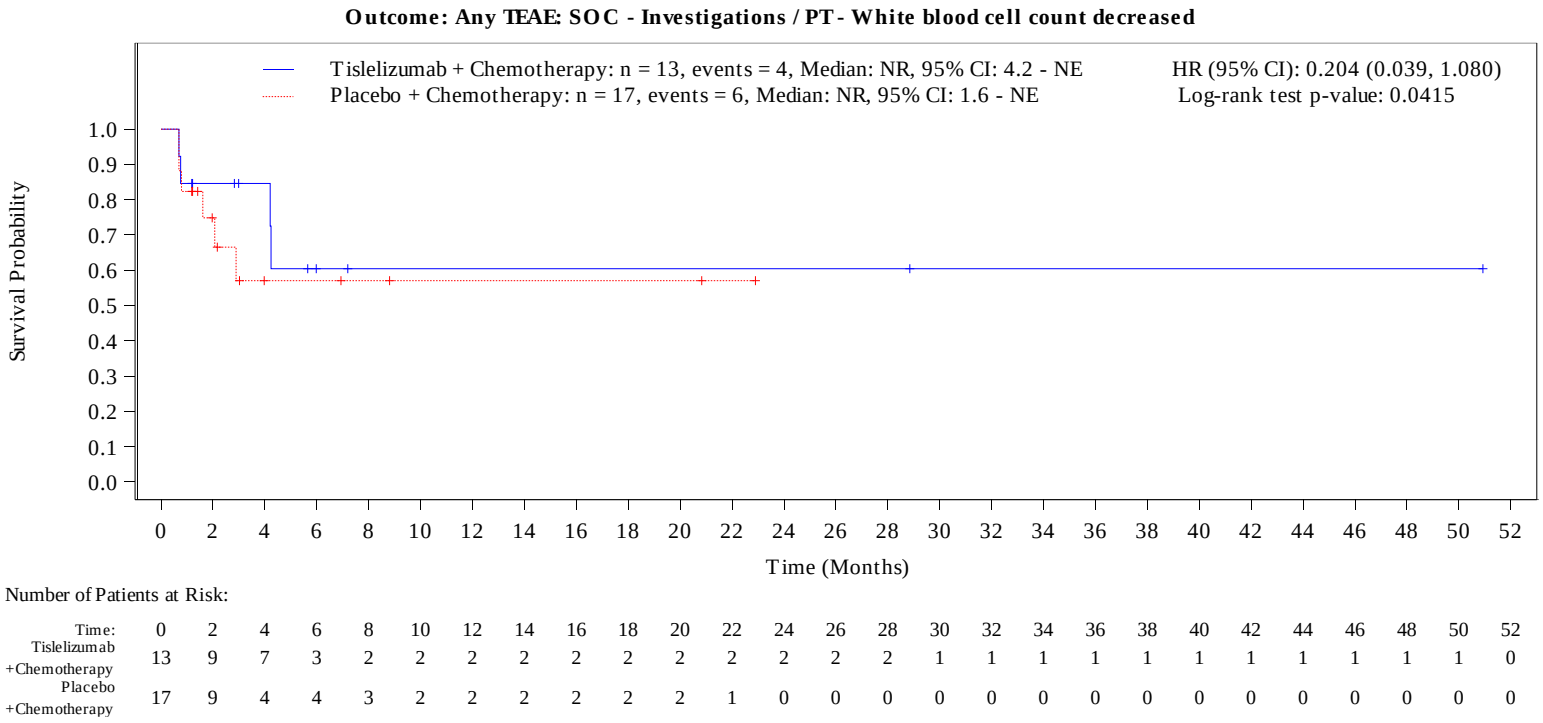

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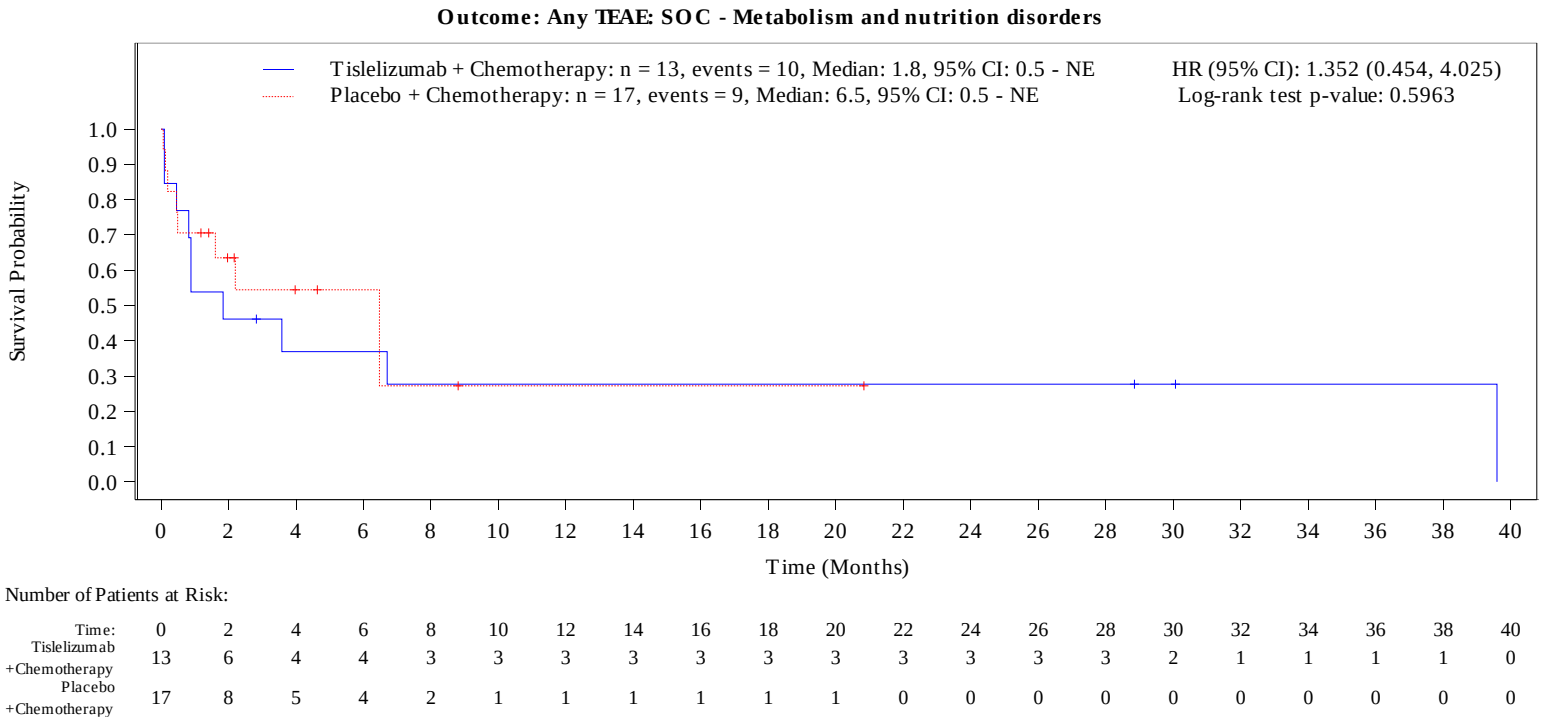

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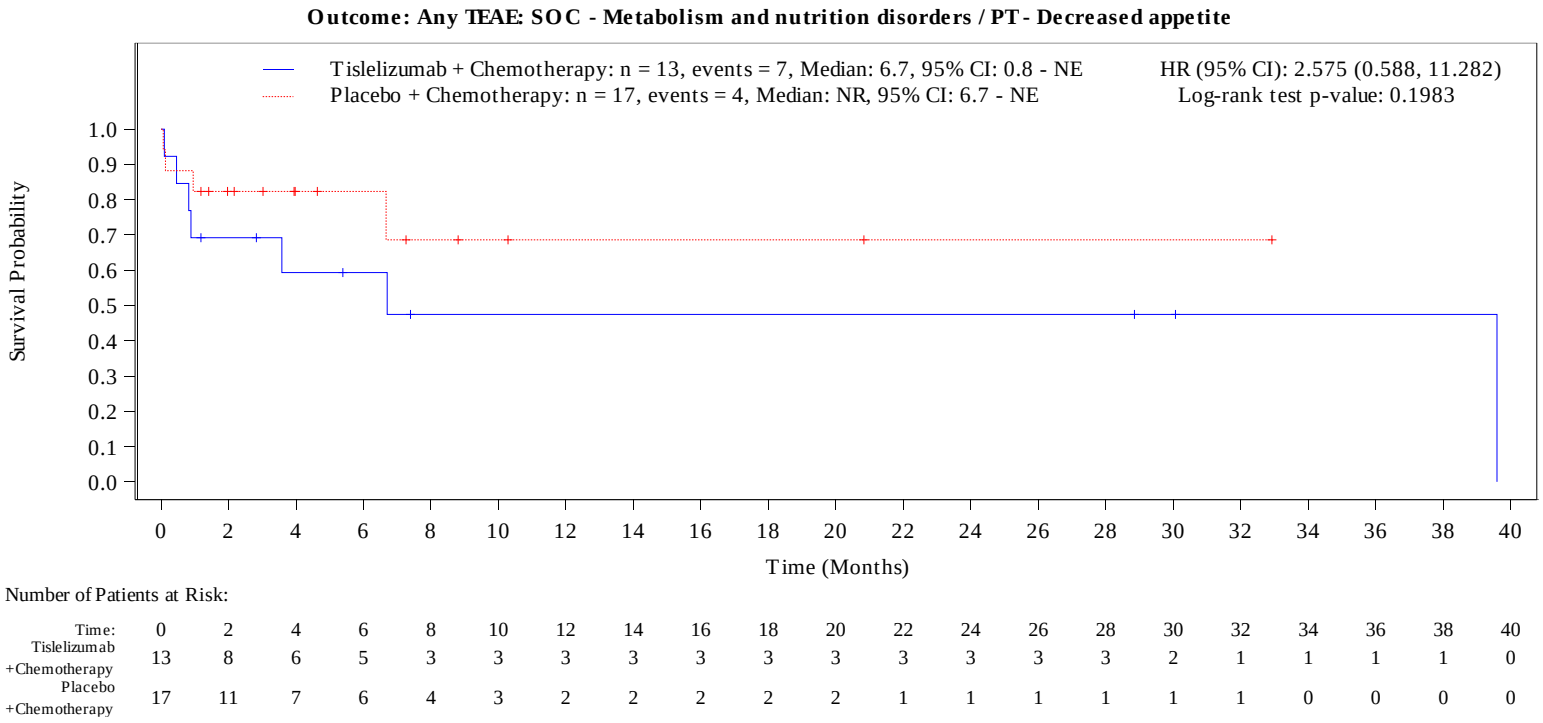

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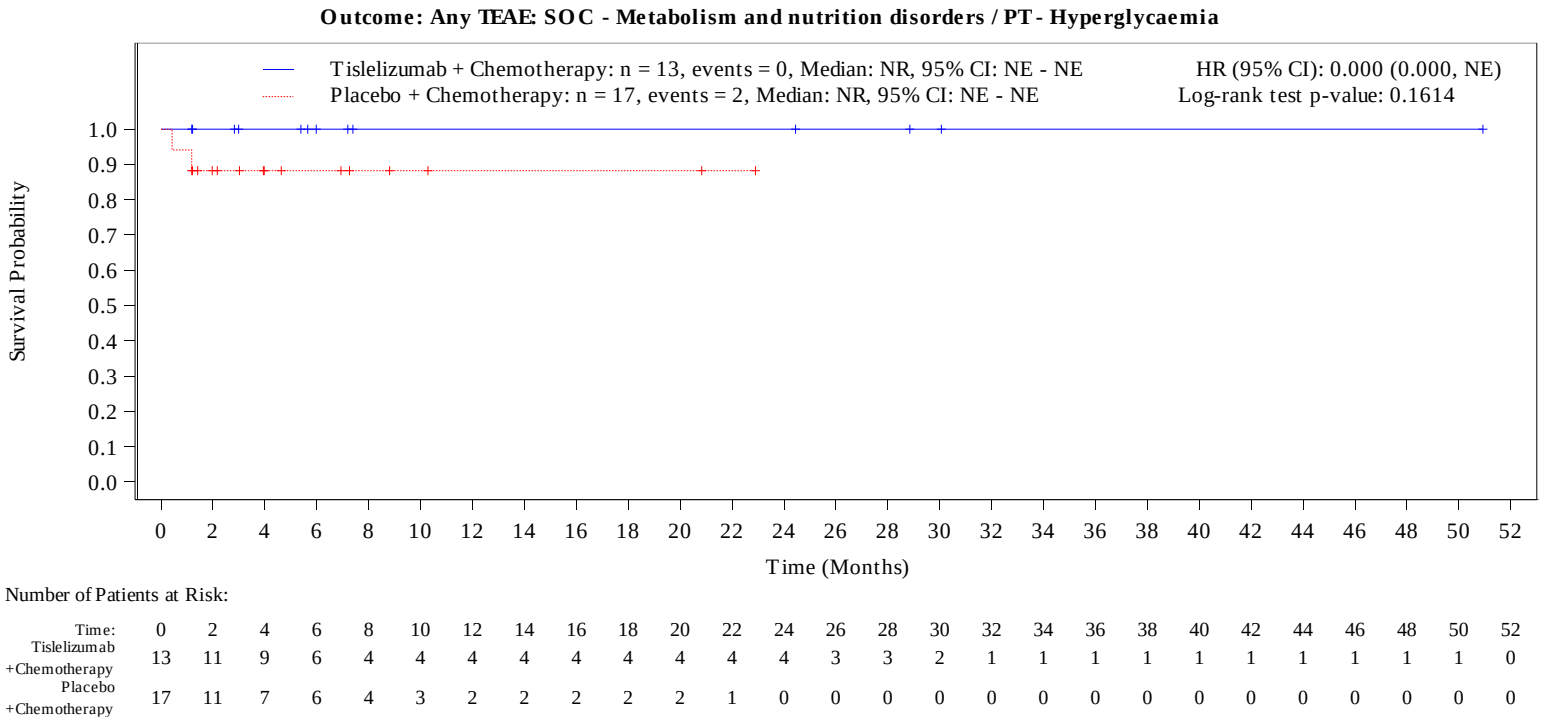

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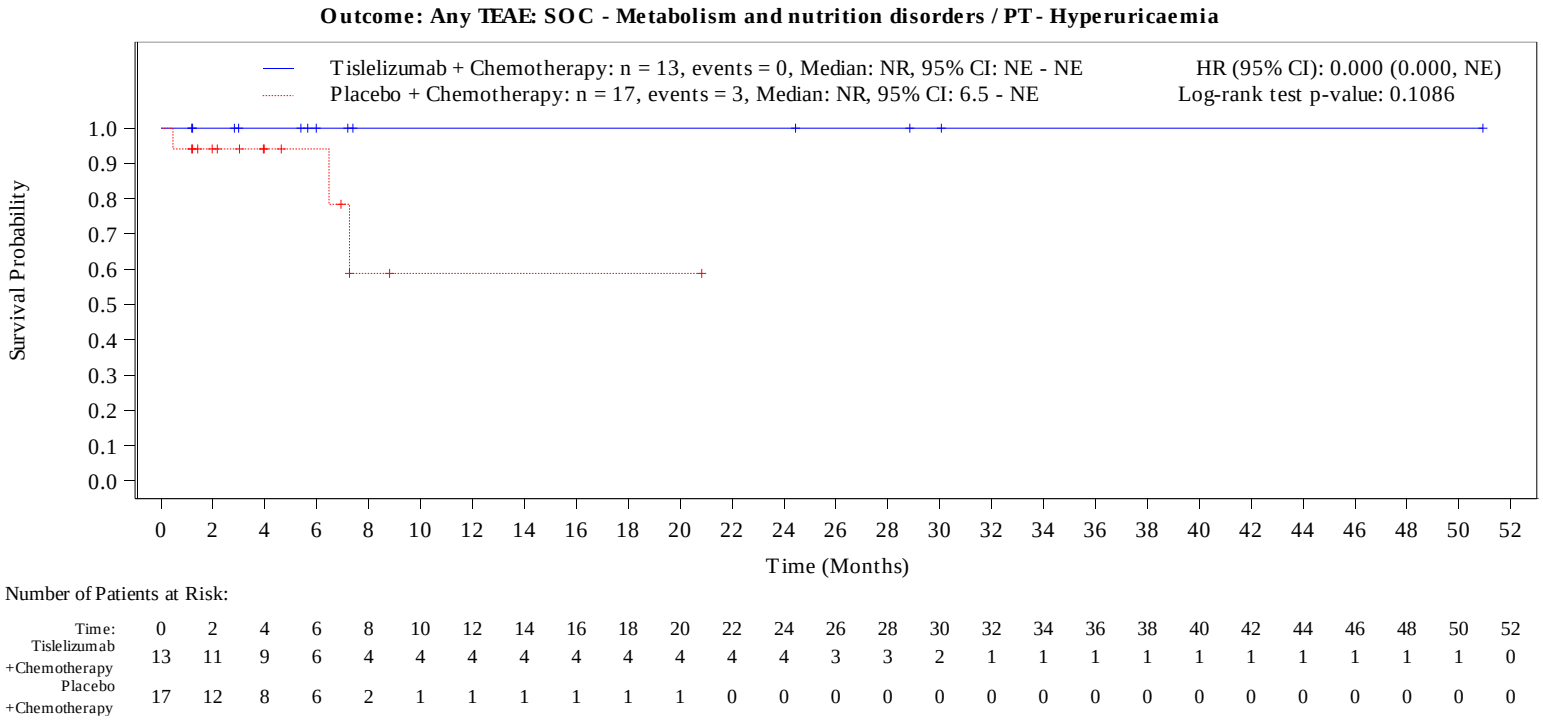

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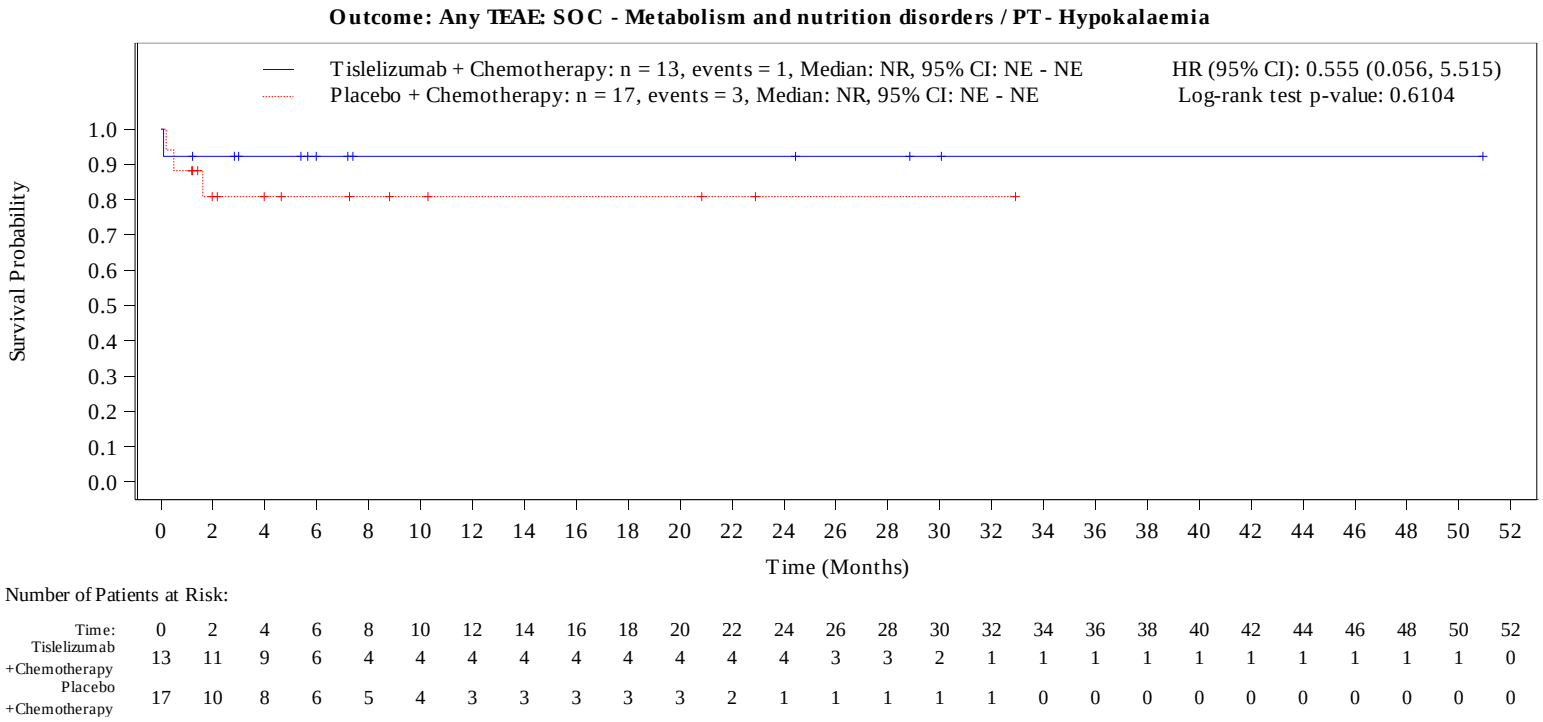

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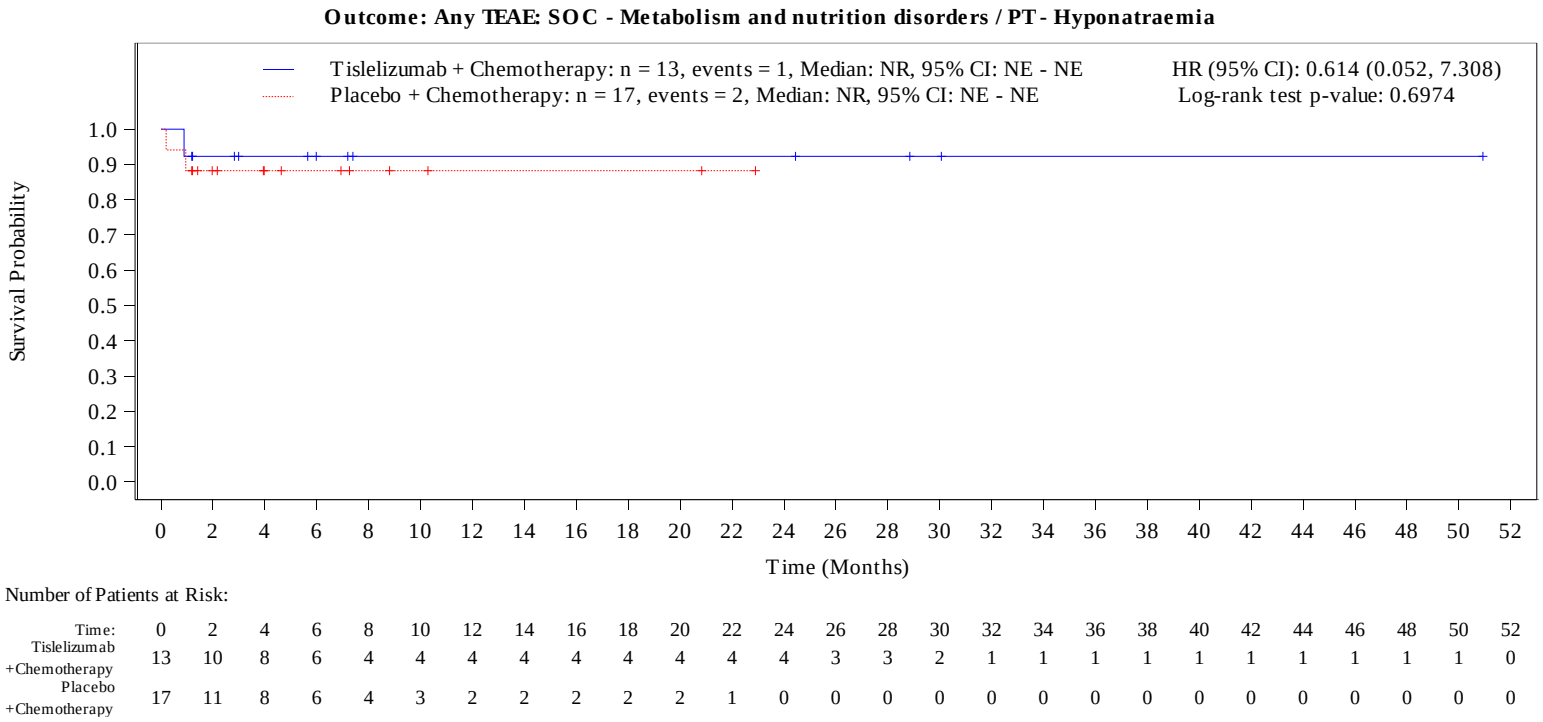

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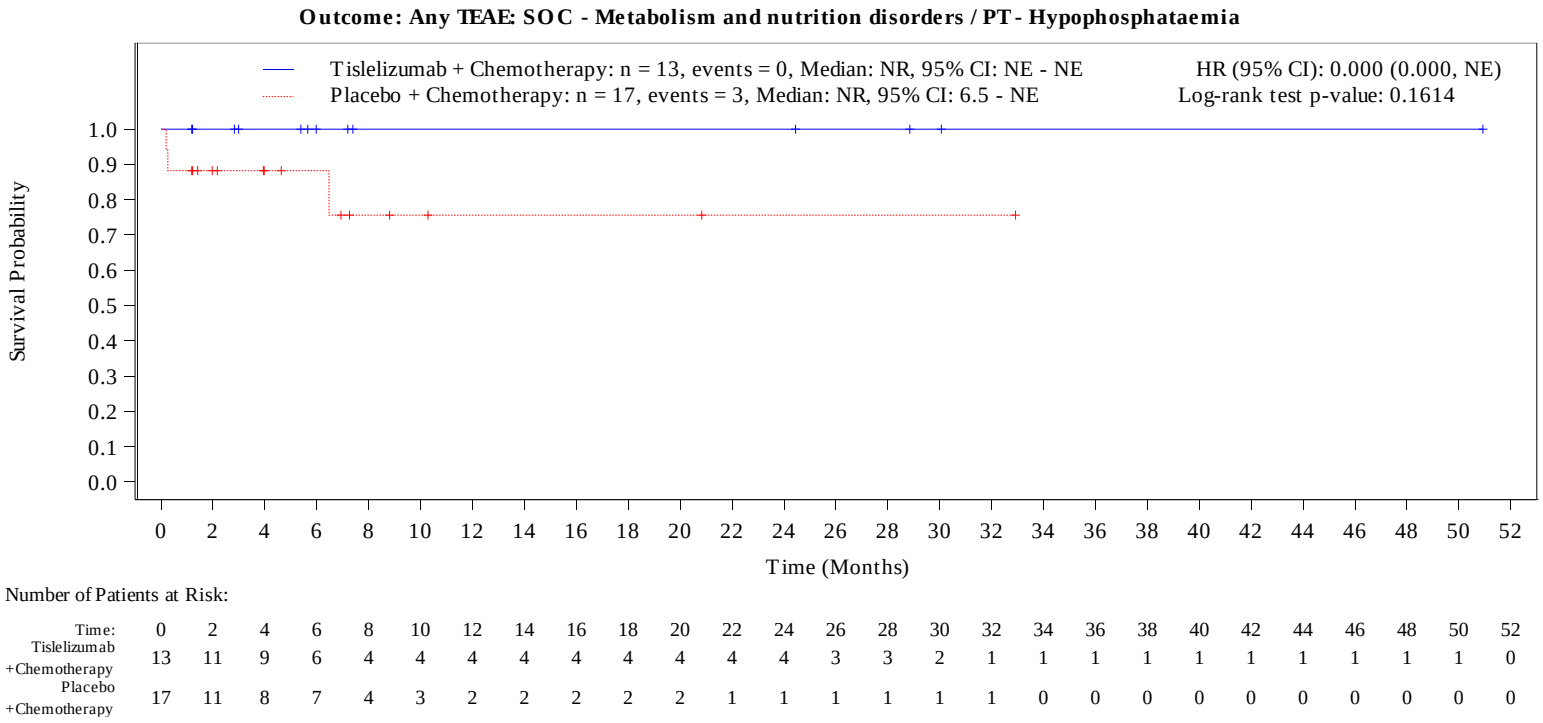

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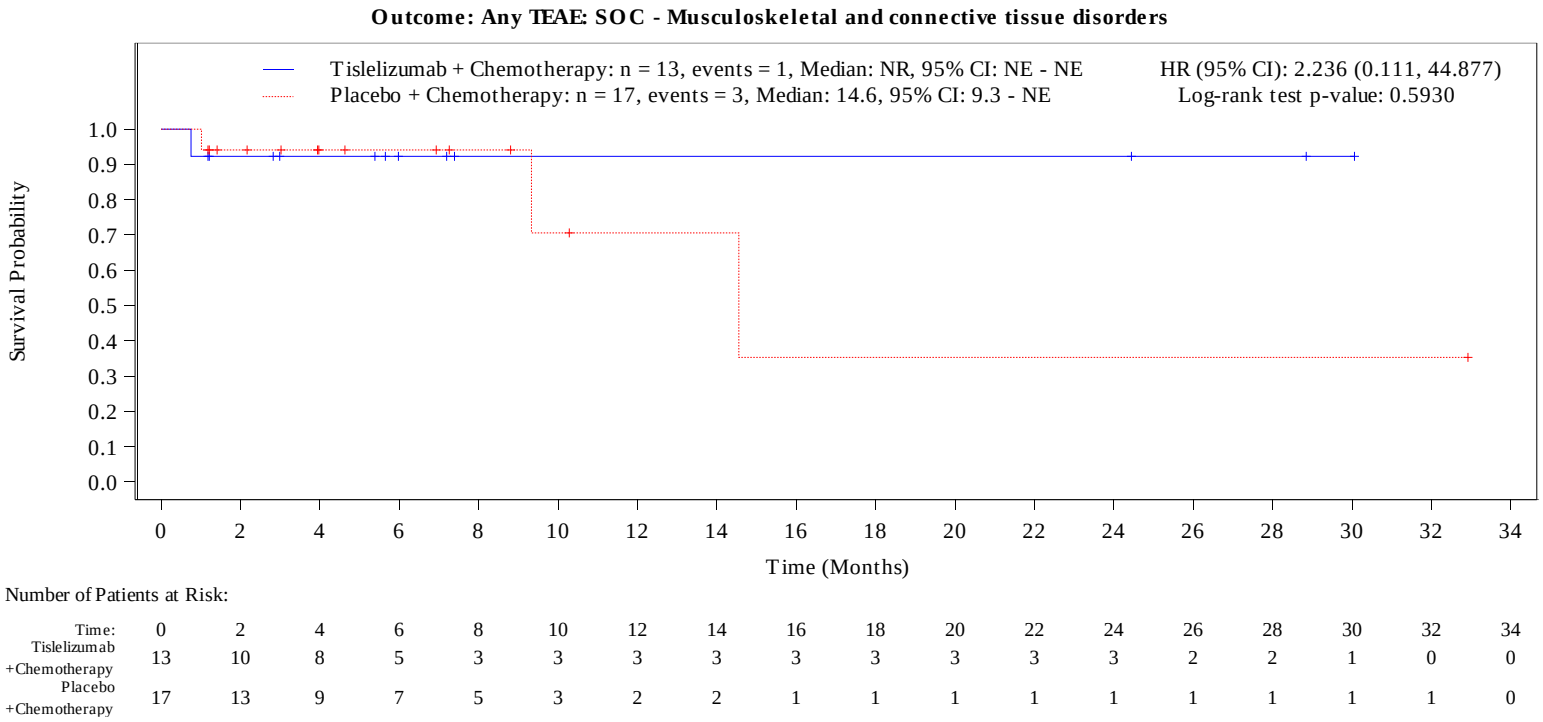

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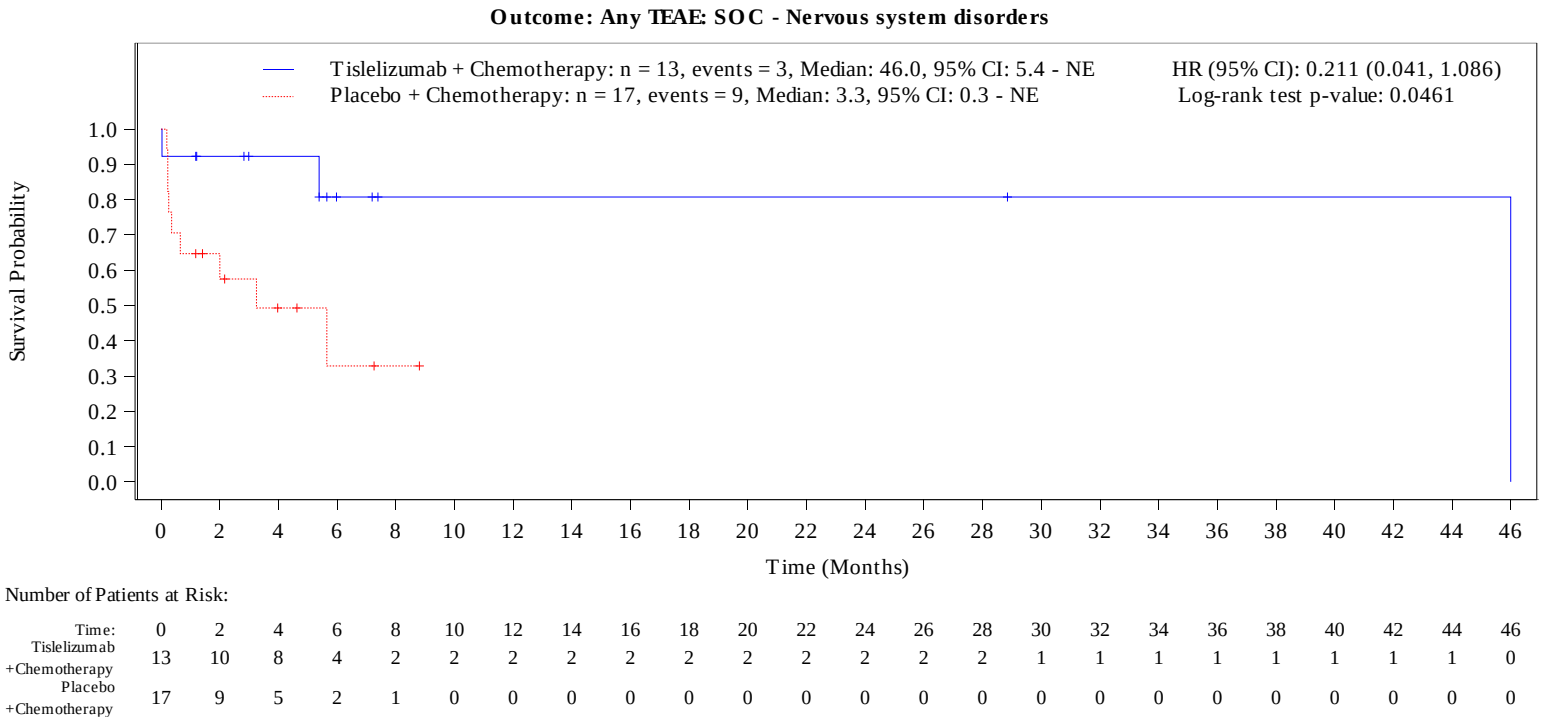

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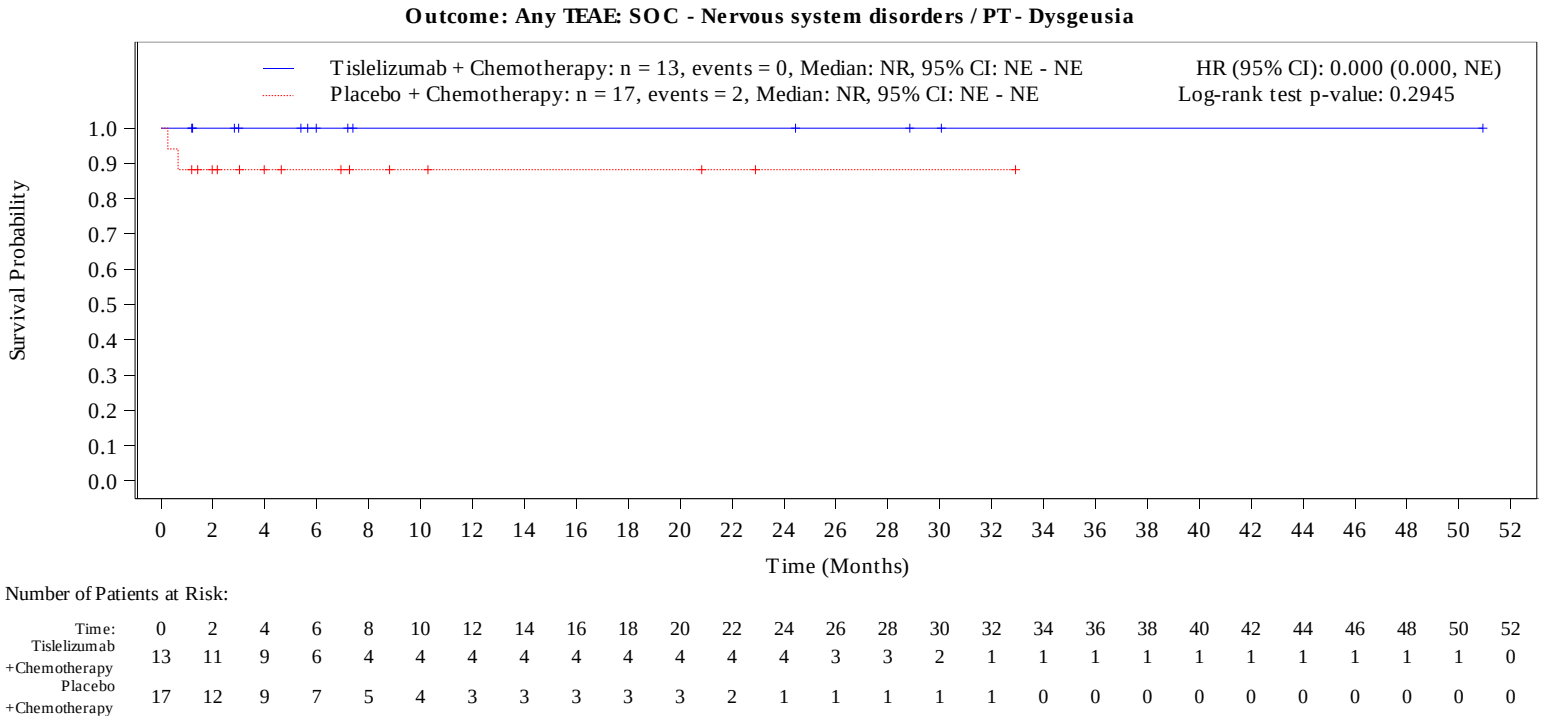

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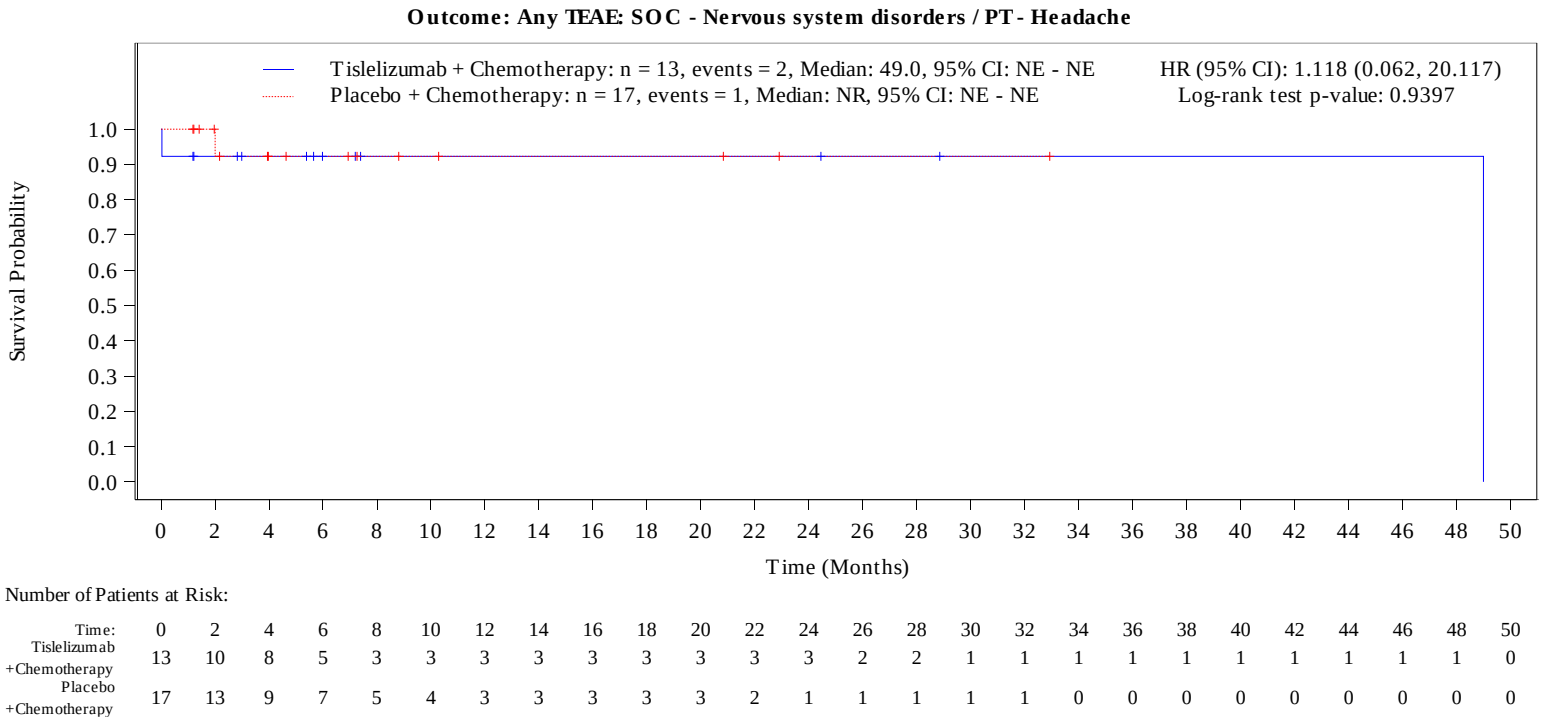

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab +Chemotherapy	13	10	8	5	3	3	3	3	3	3	3	3	3	2	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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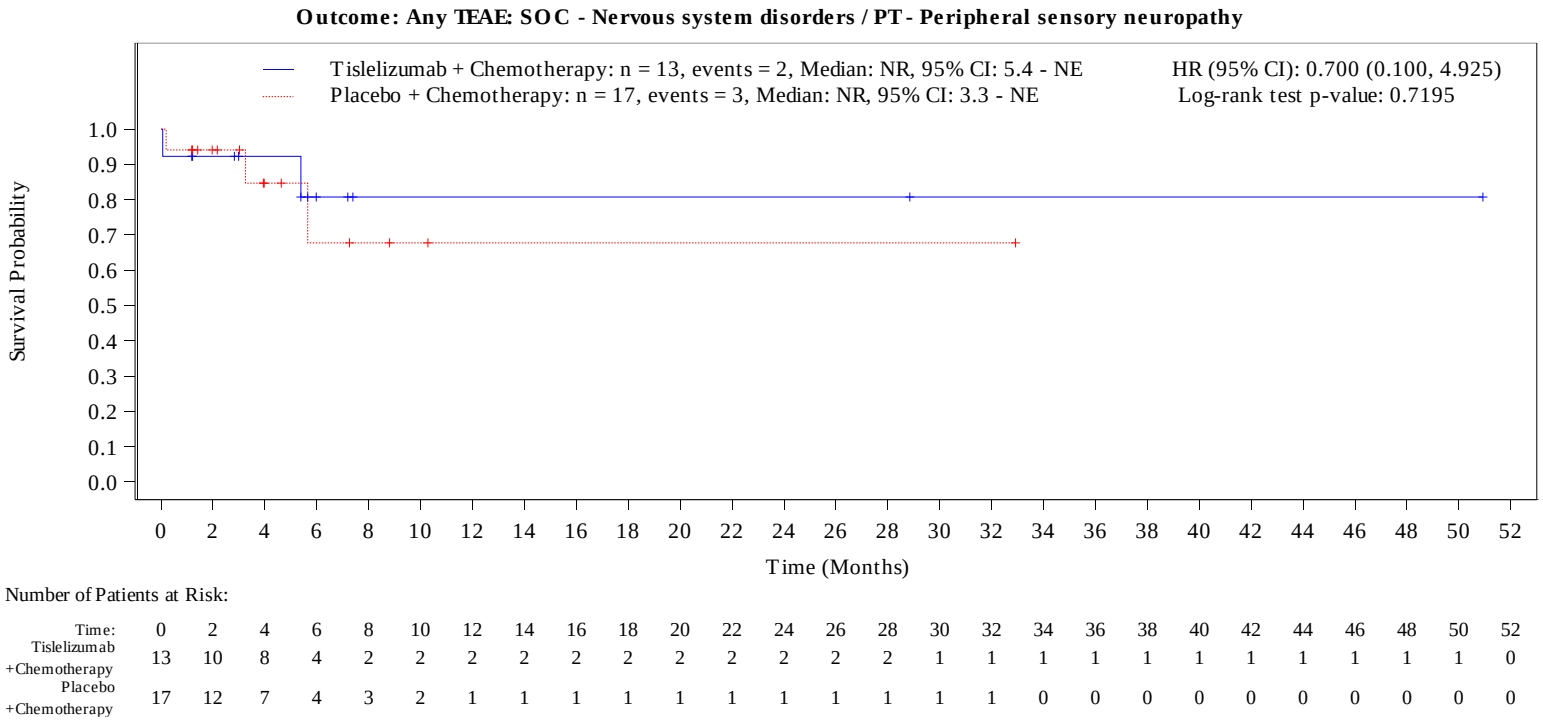
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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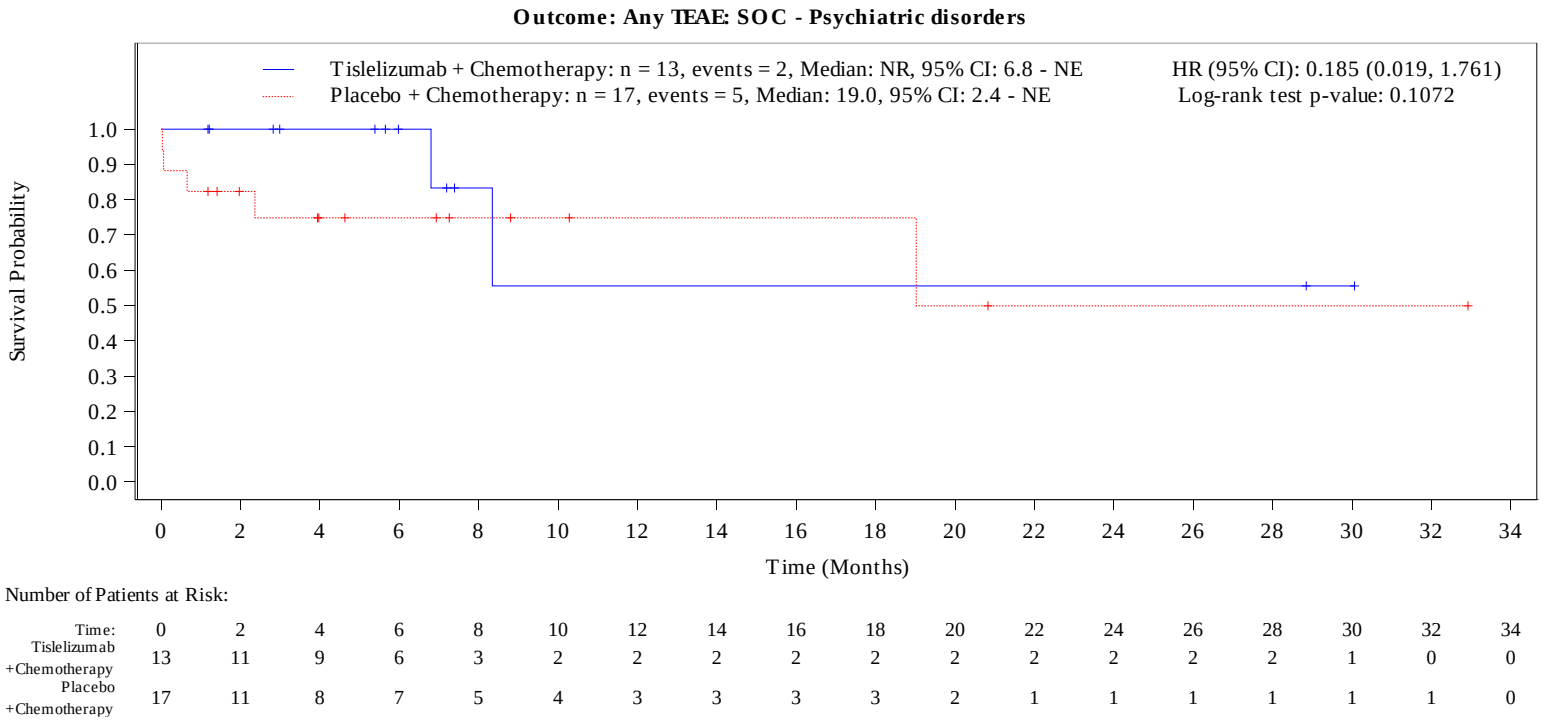
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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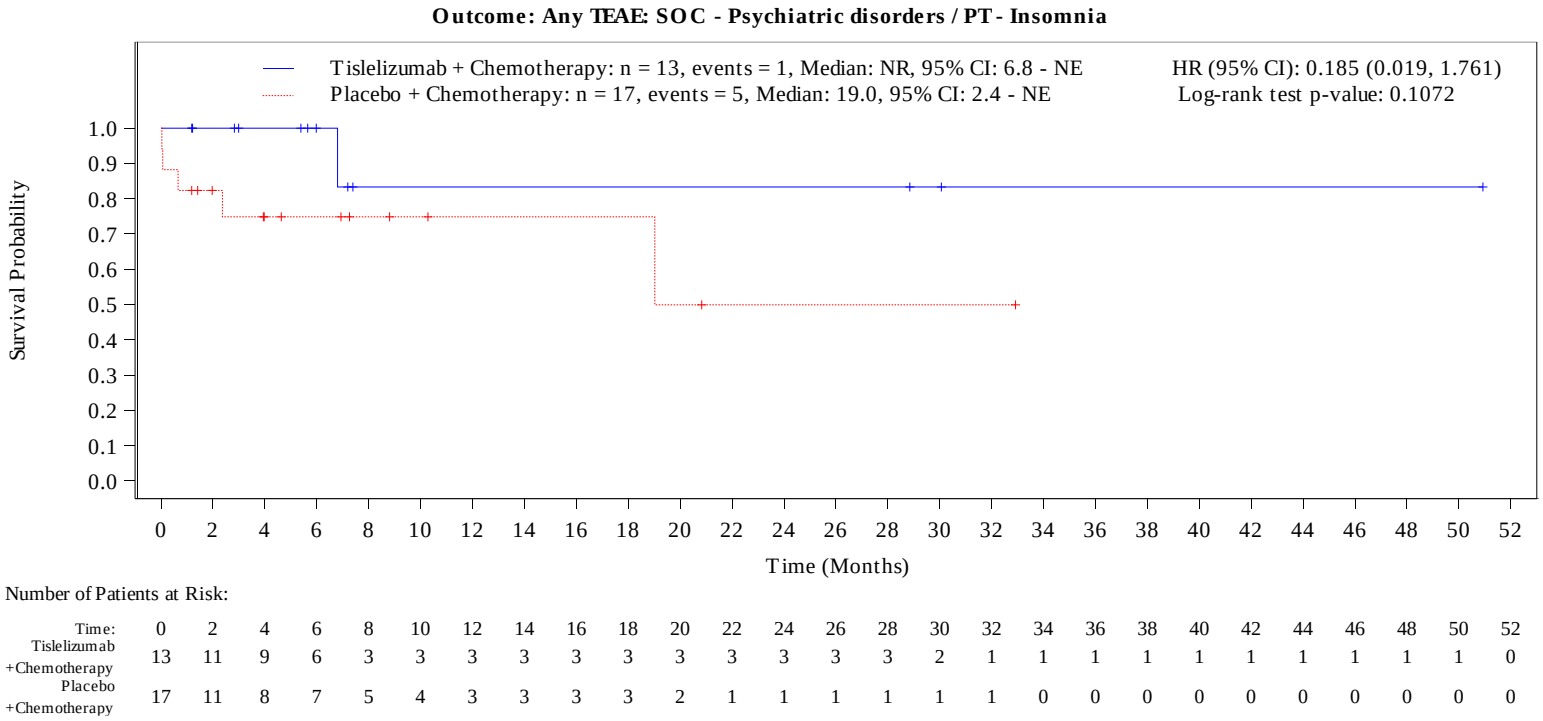
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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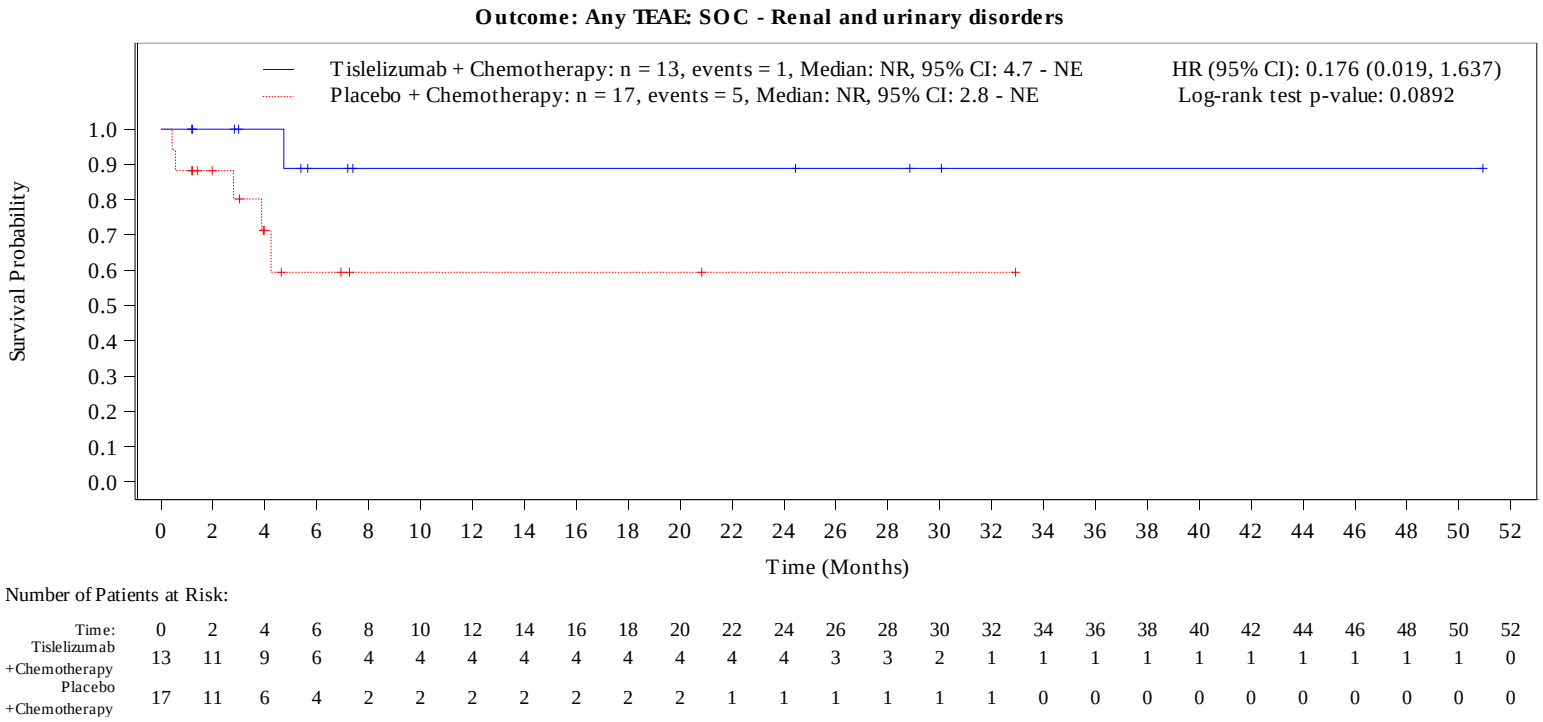
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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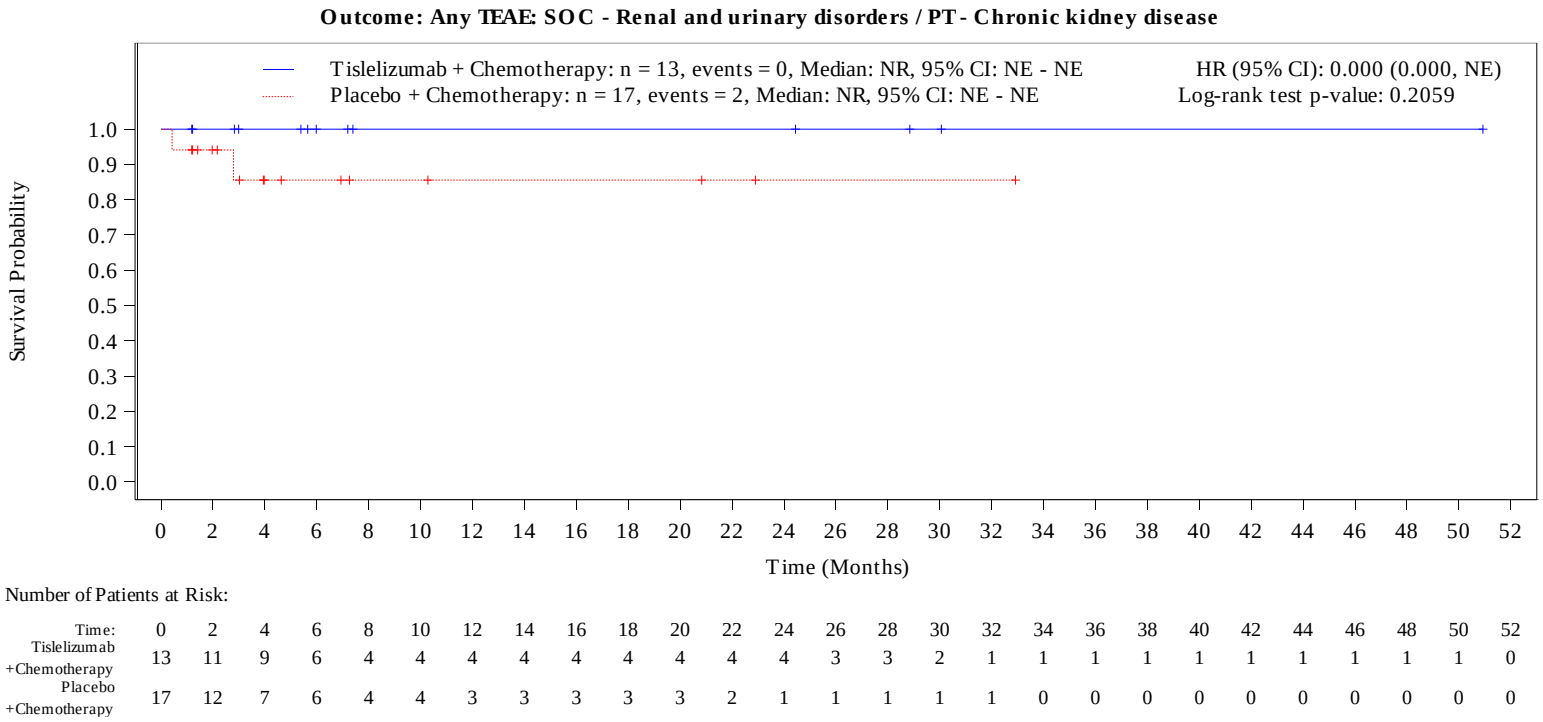
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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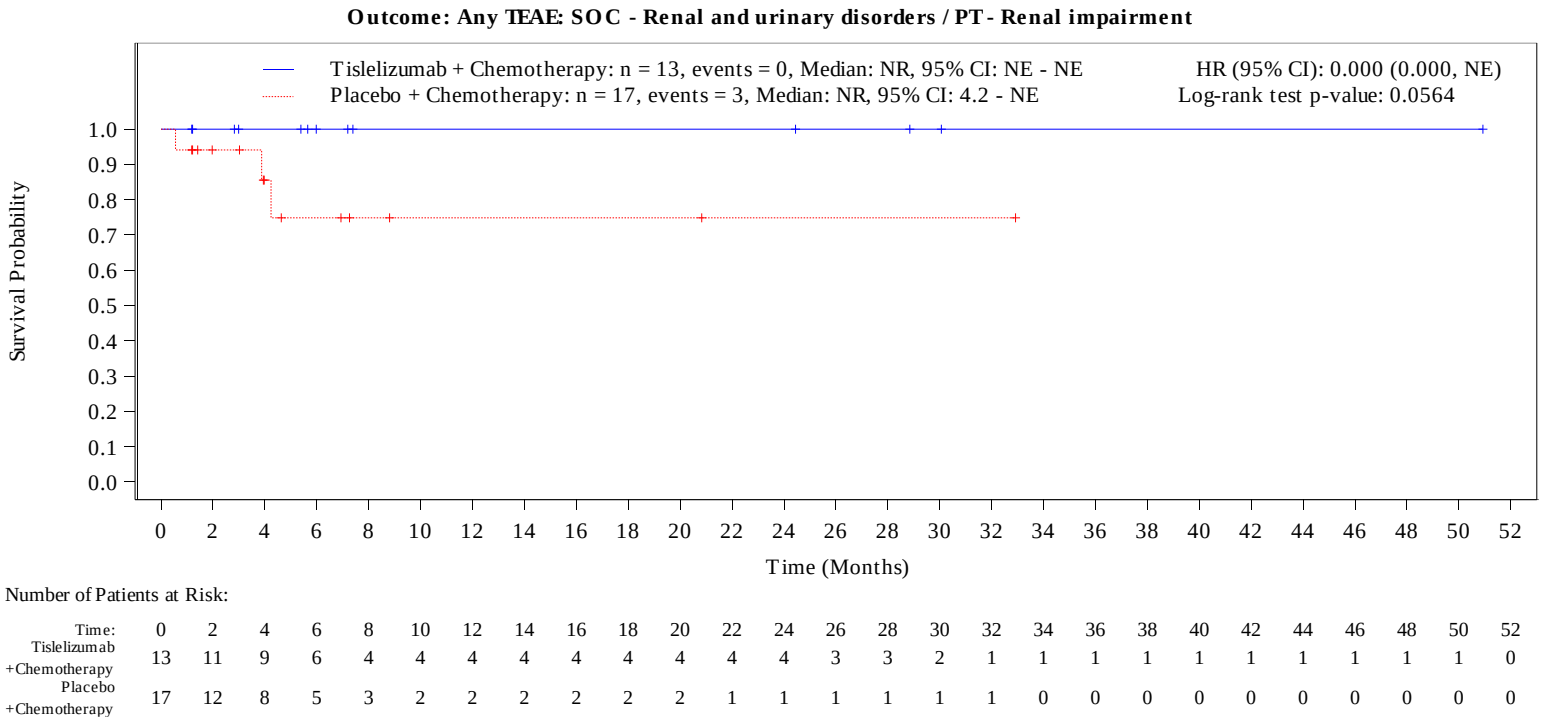
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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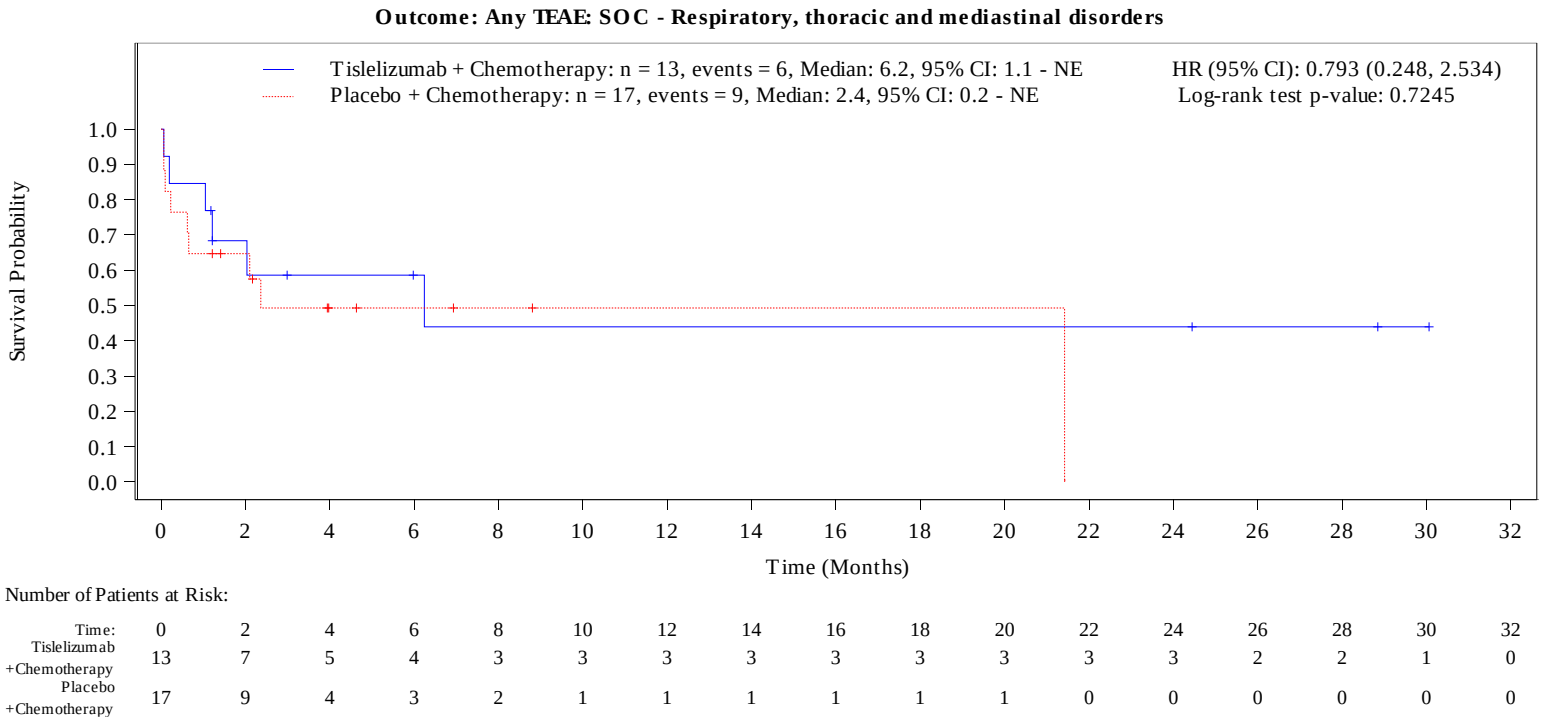
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab +Chemotherapy	13	7	5	4	3	3	3	3	3	3	3	3	3	2	2	1	0
Placebo +Chemotherapy	17	9	4	3	2	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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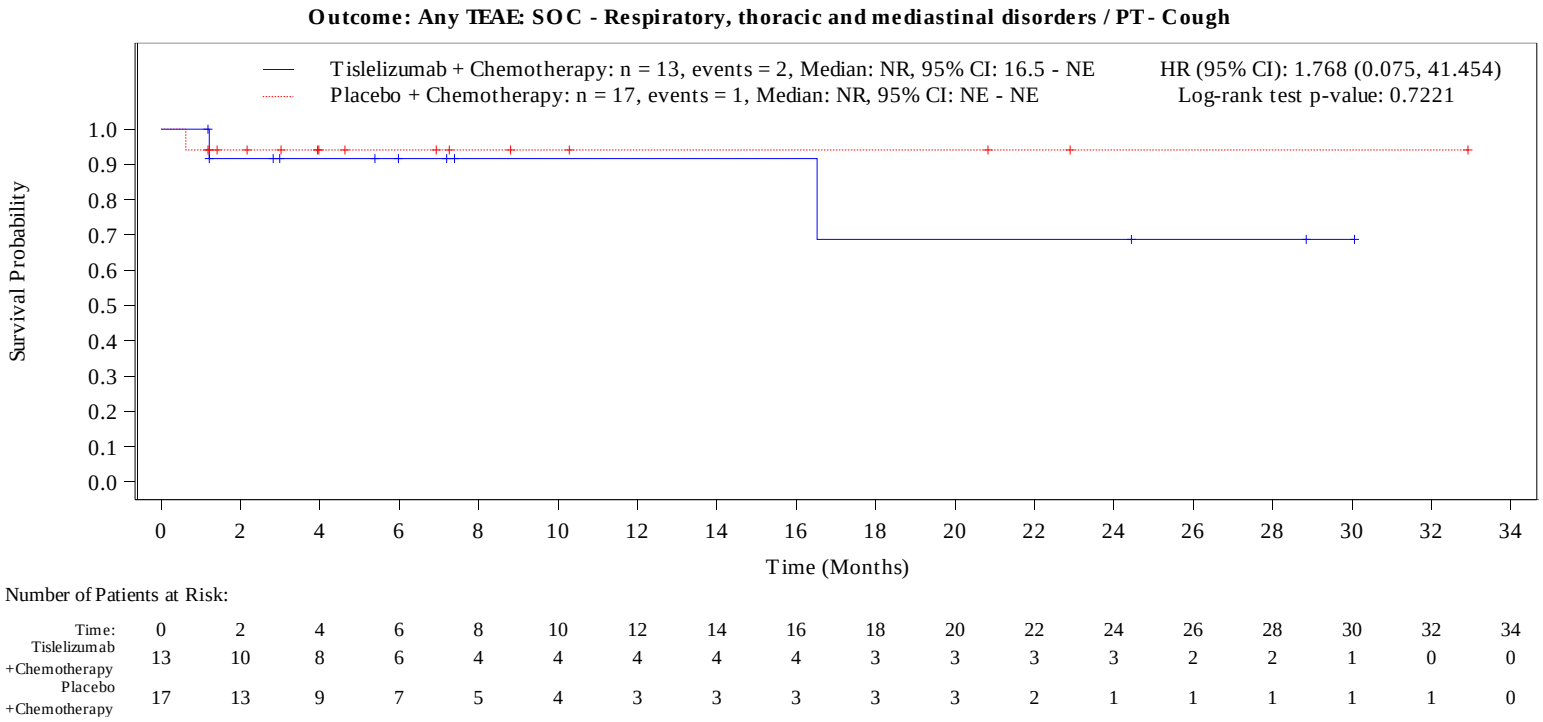
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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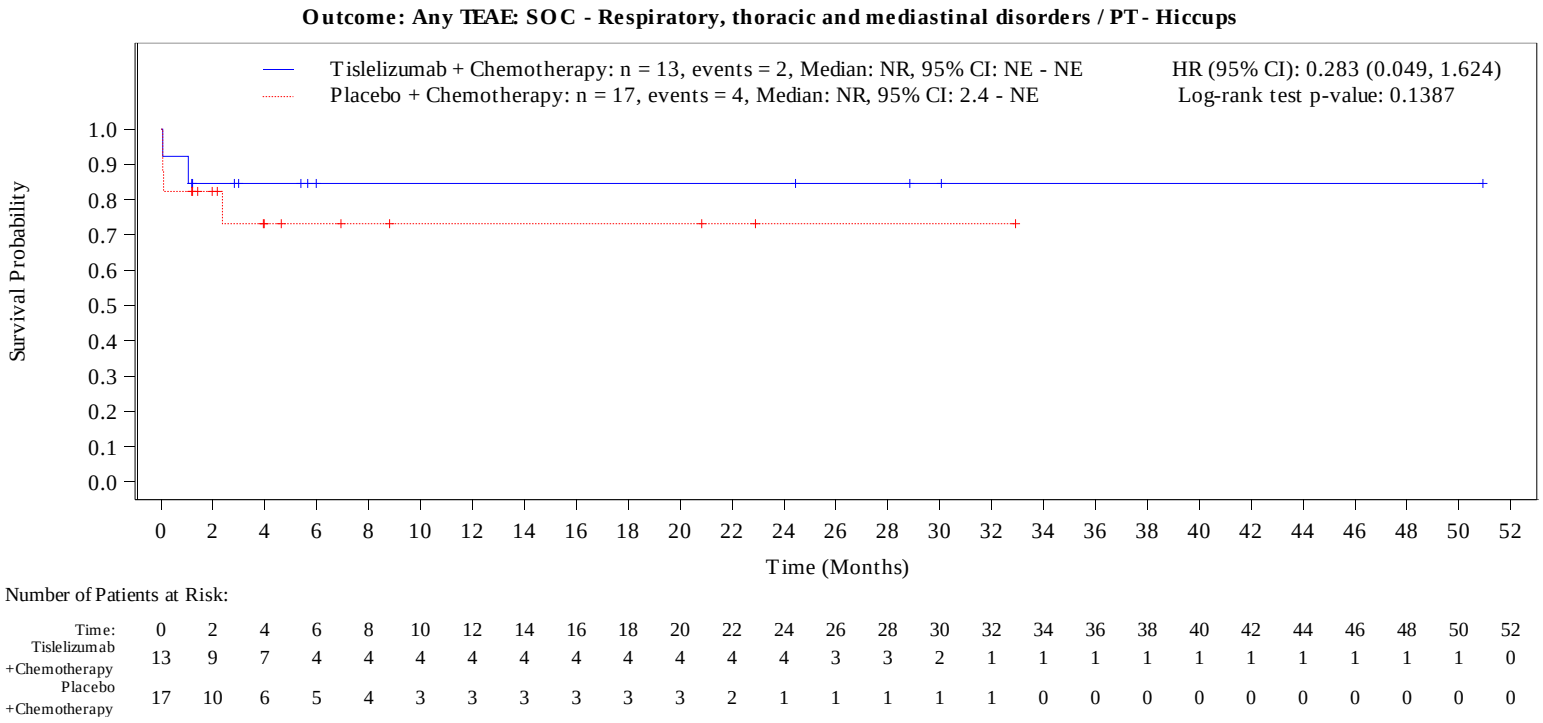
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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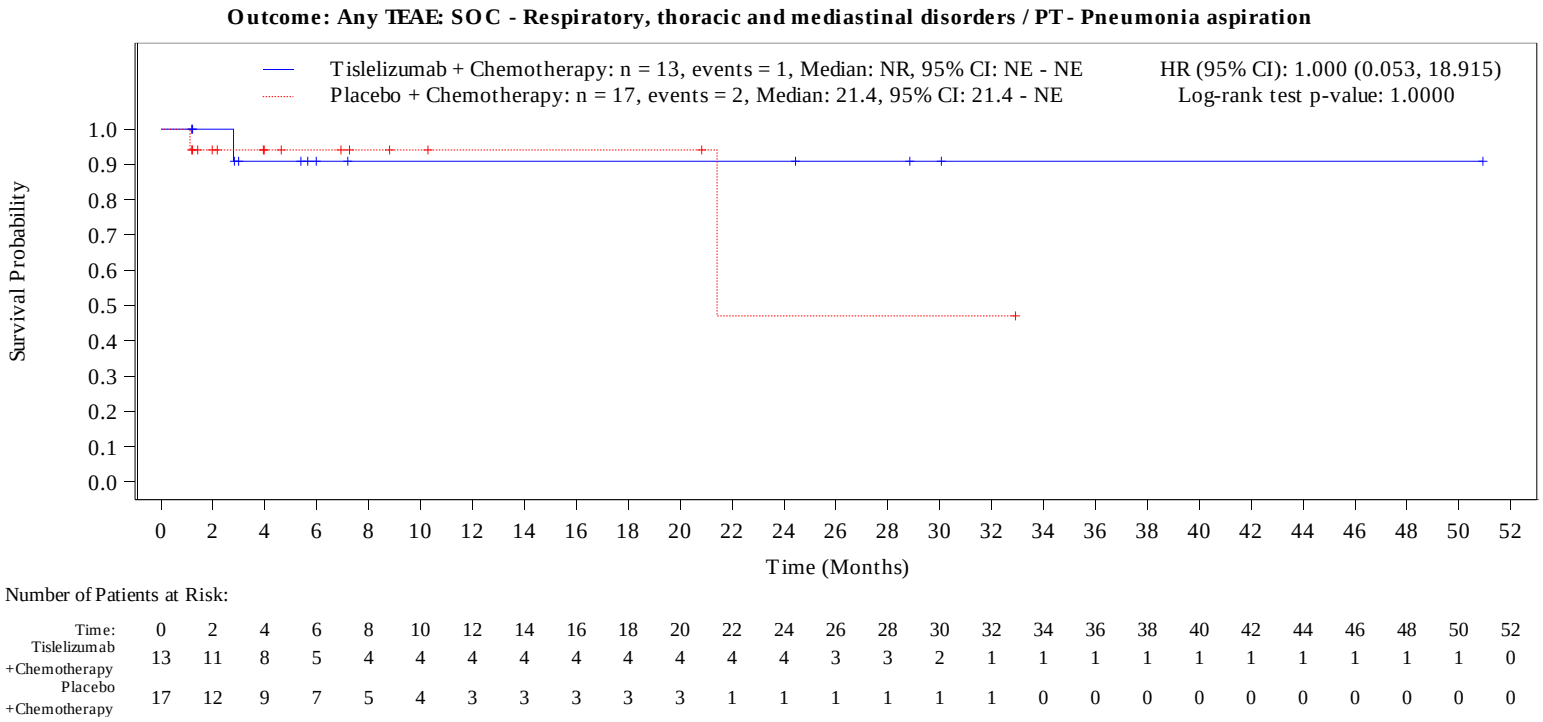
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

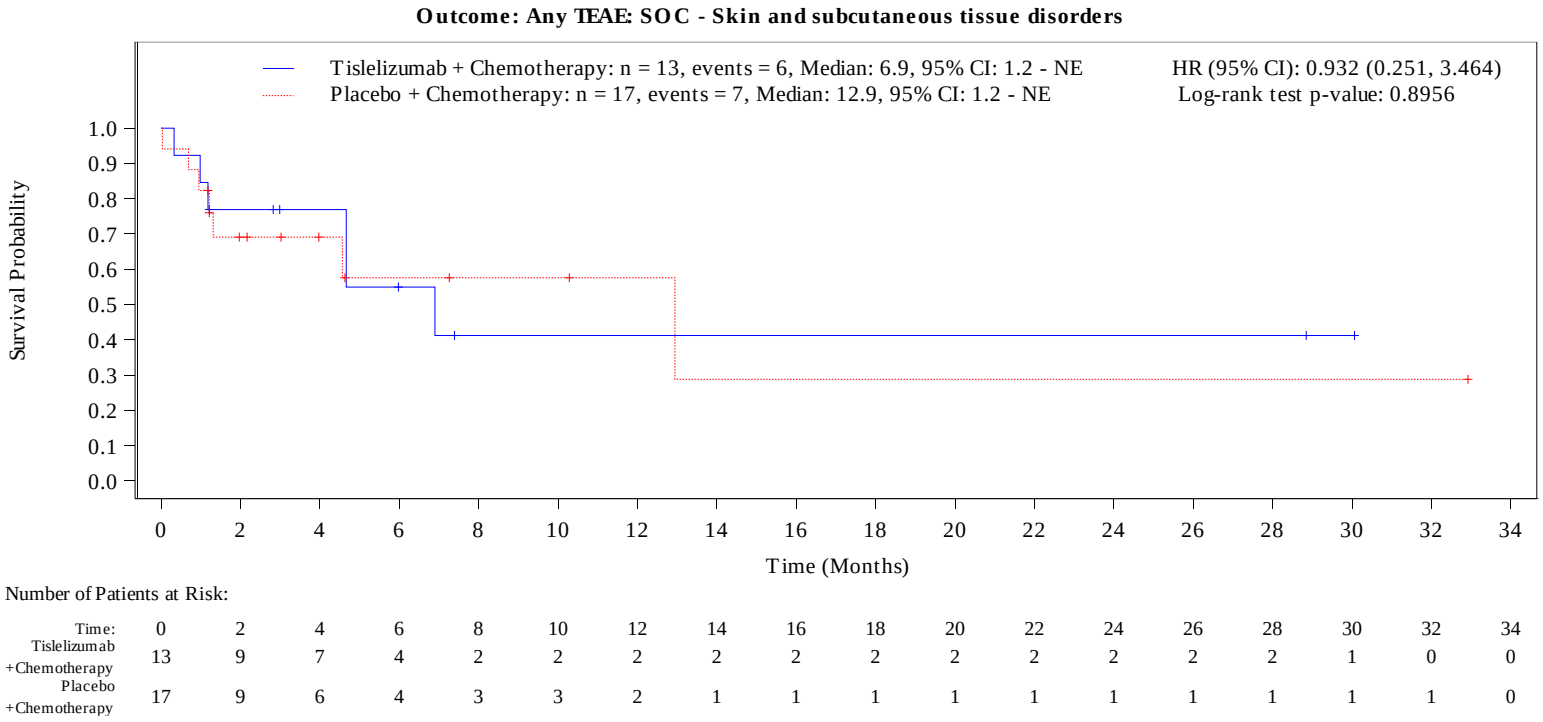

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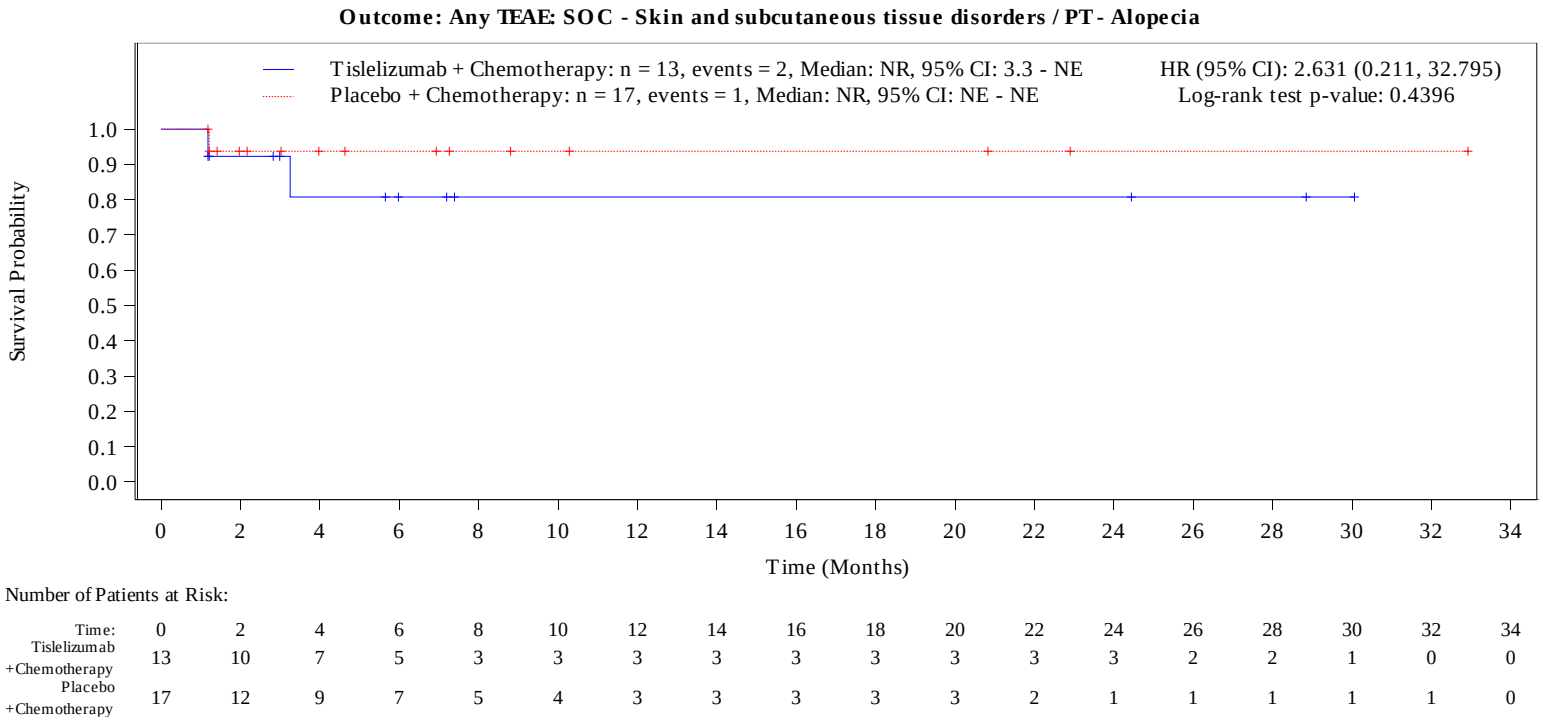
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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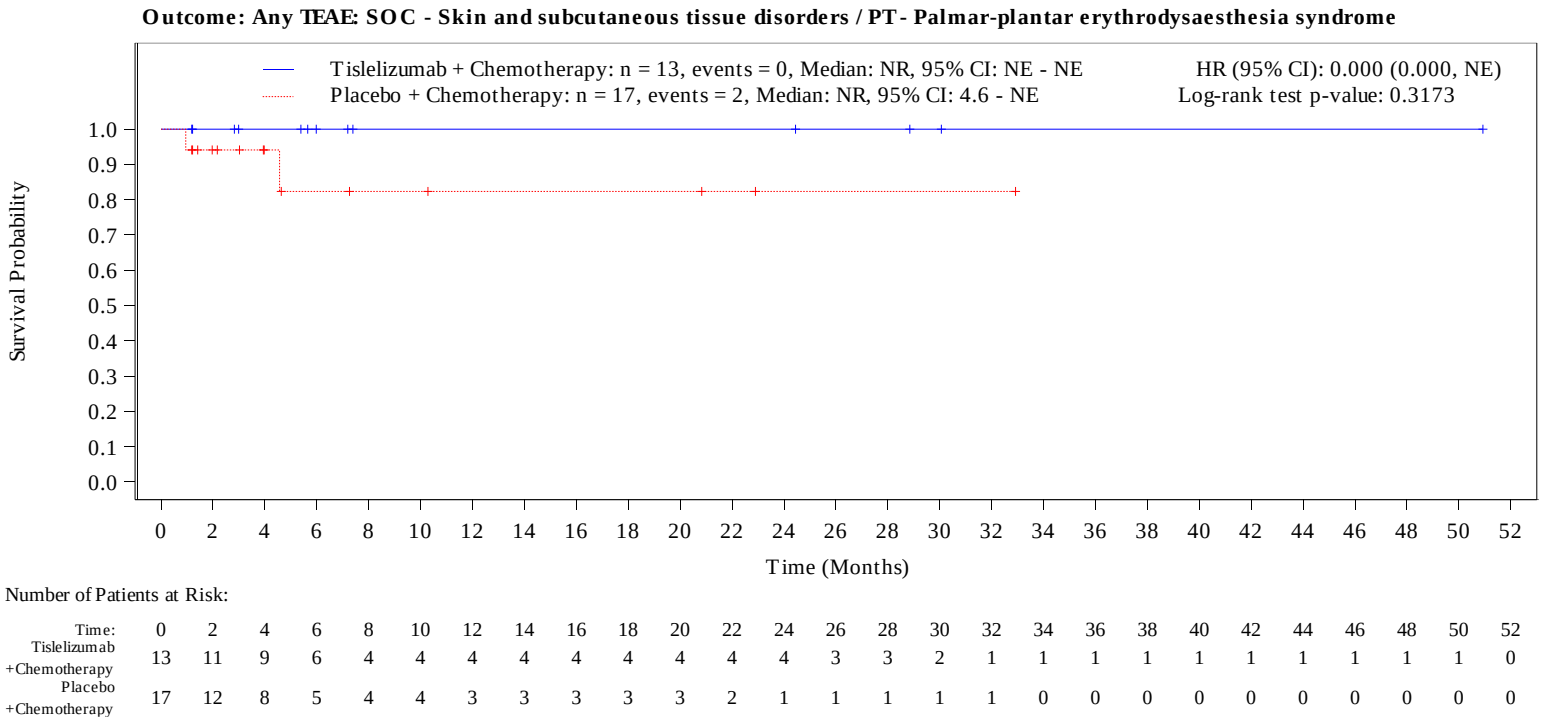
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	8	5	4	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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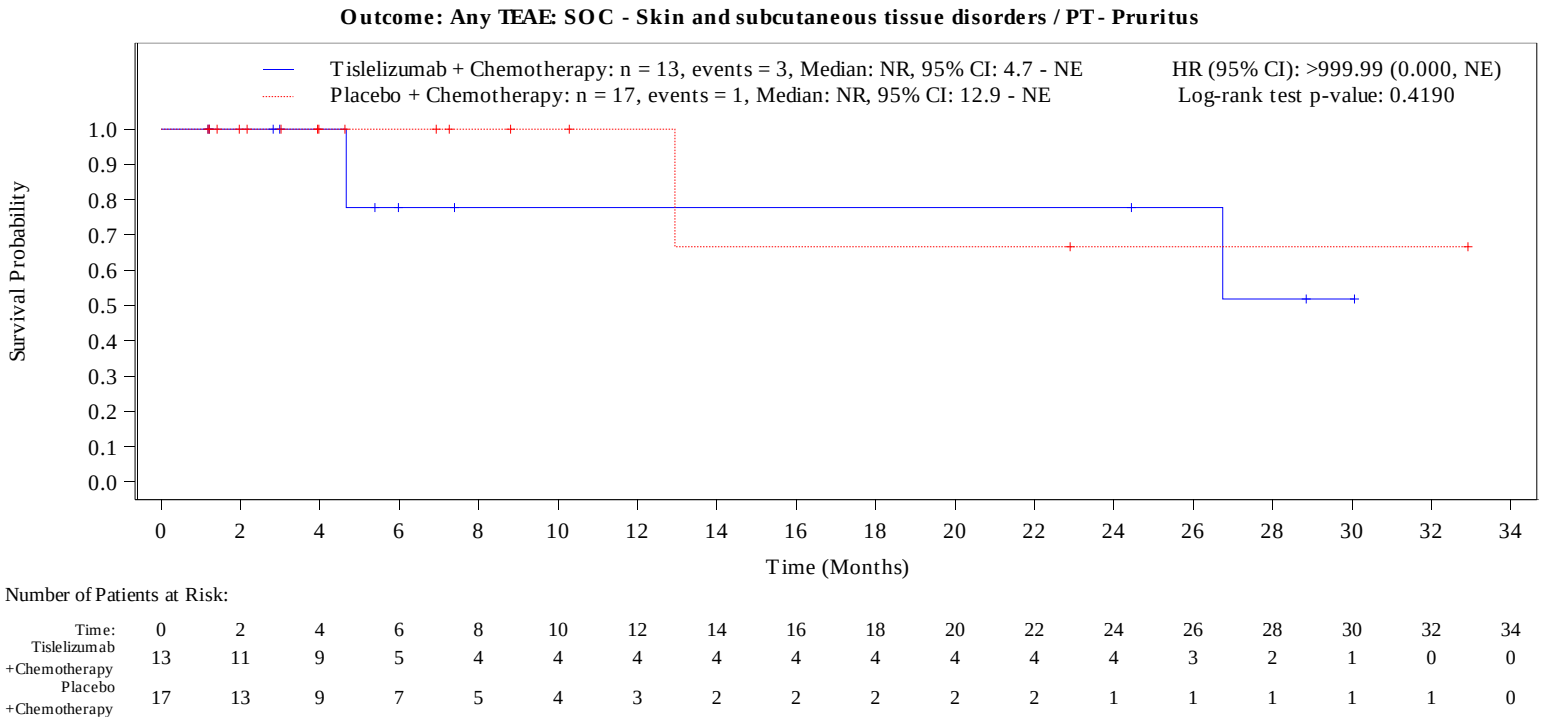
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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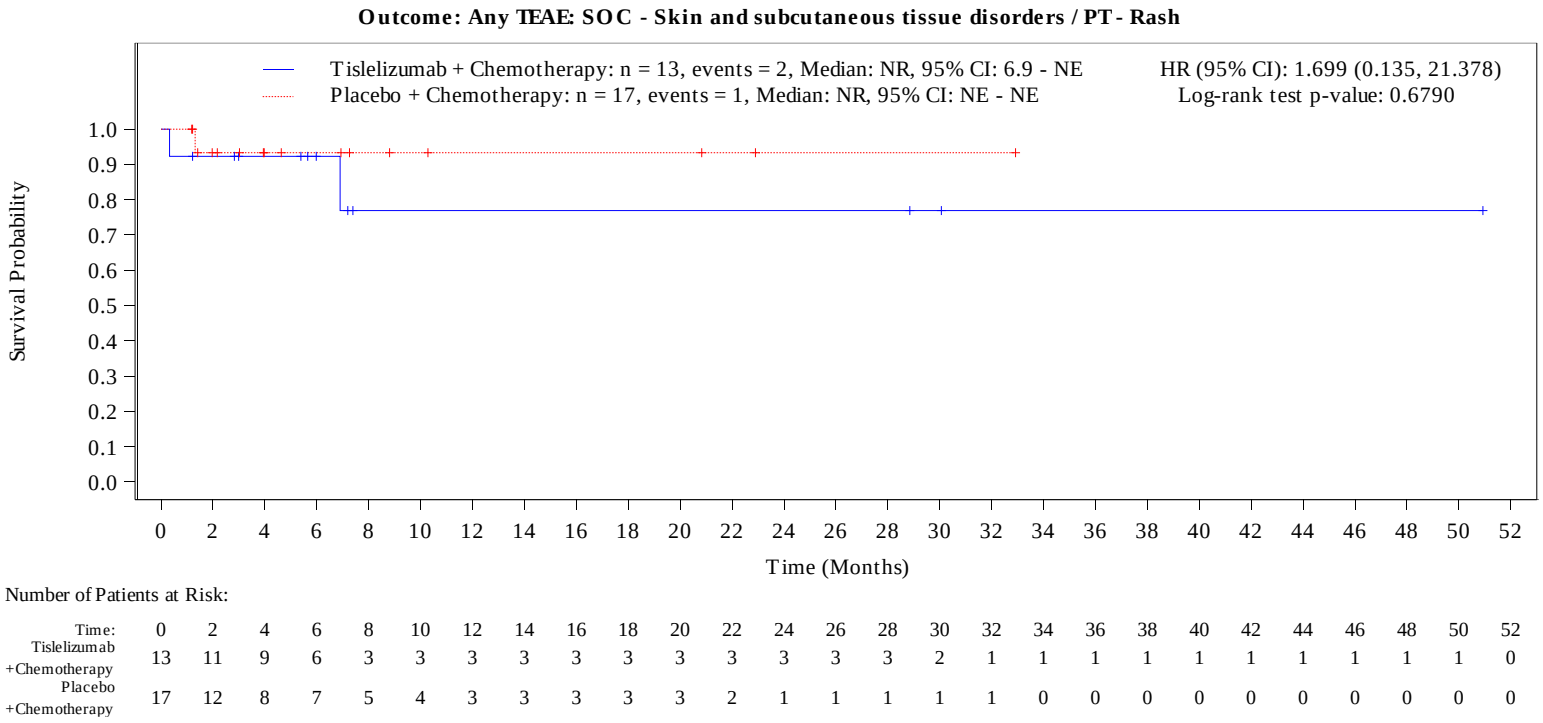
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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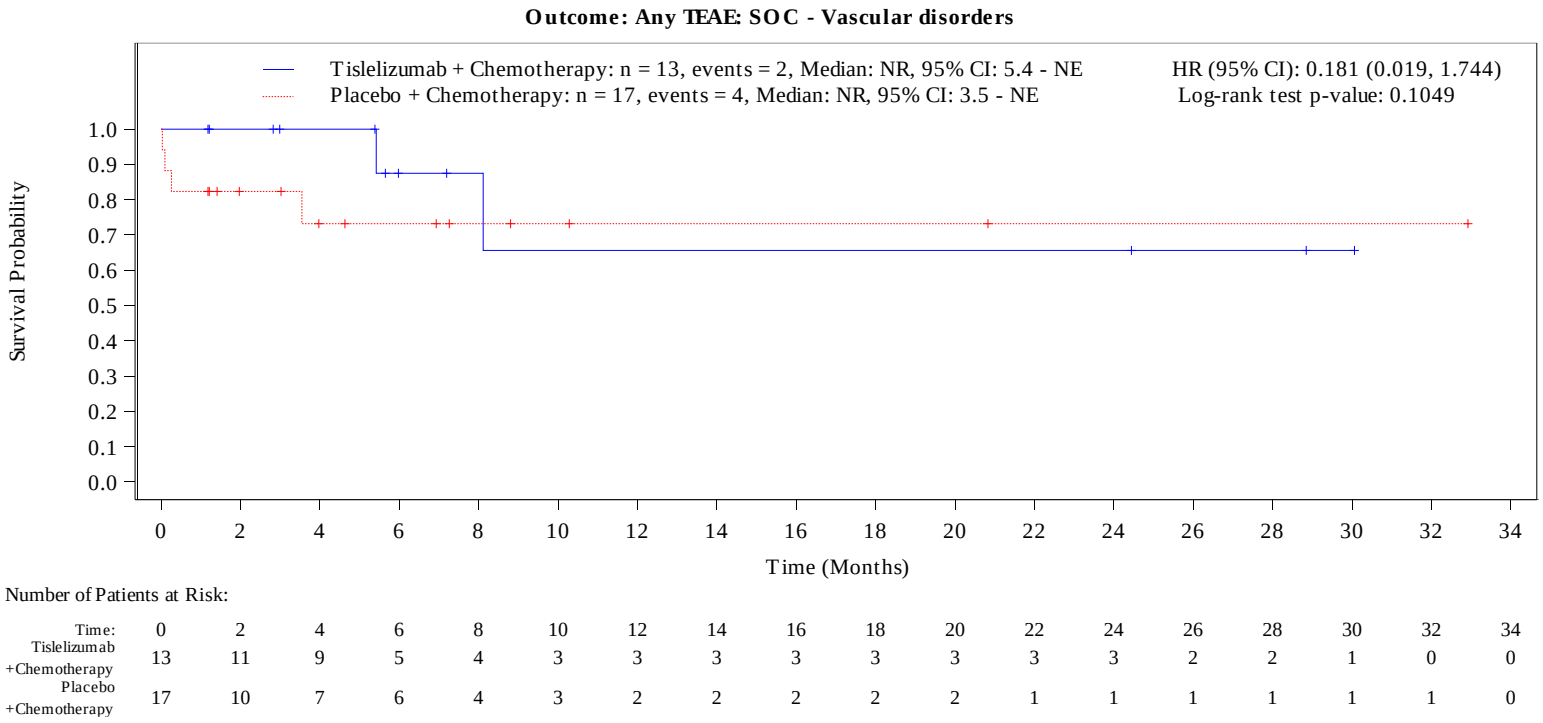
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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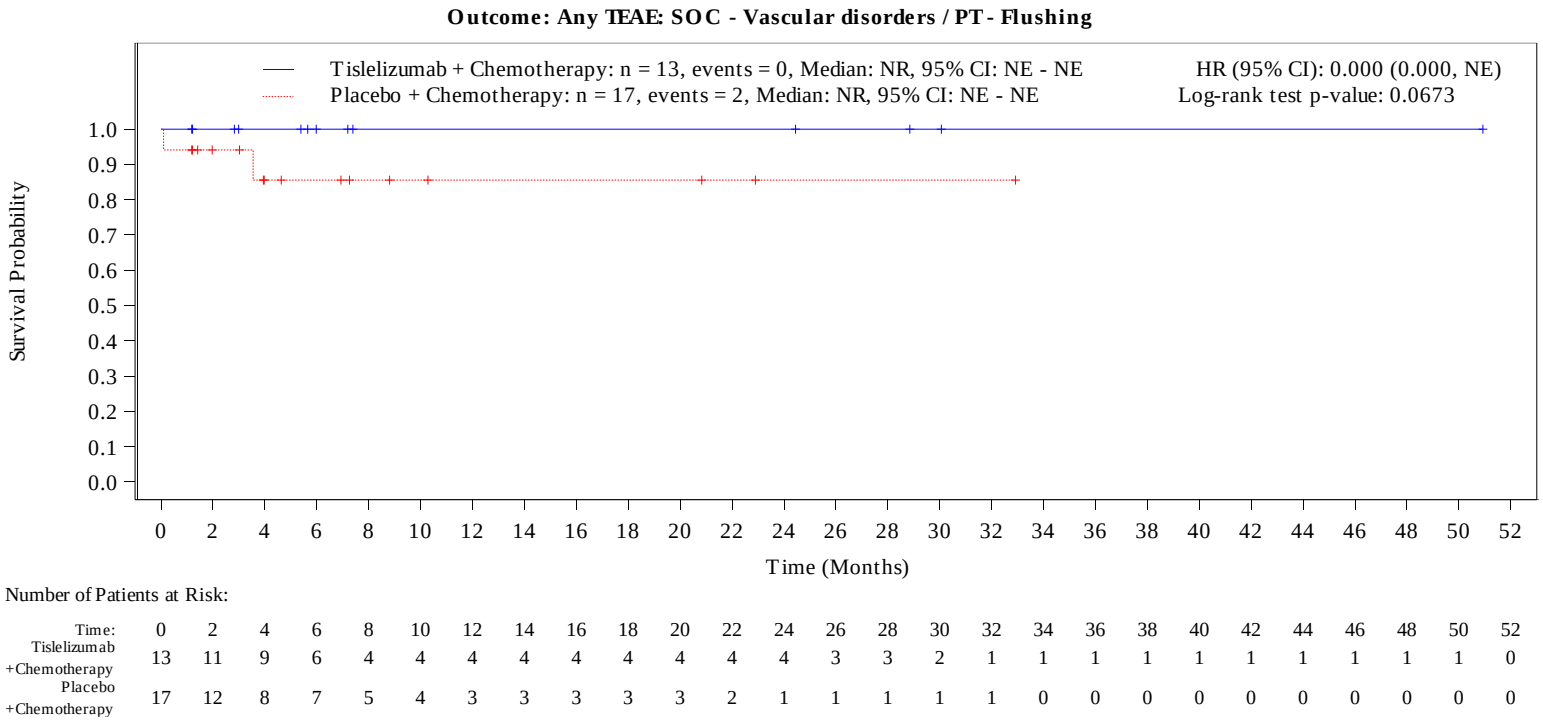
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-2-km-aesocpt-teae-pop1-3y.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	8	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-2-km-aesocpt-teae-pop1-3y.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

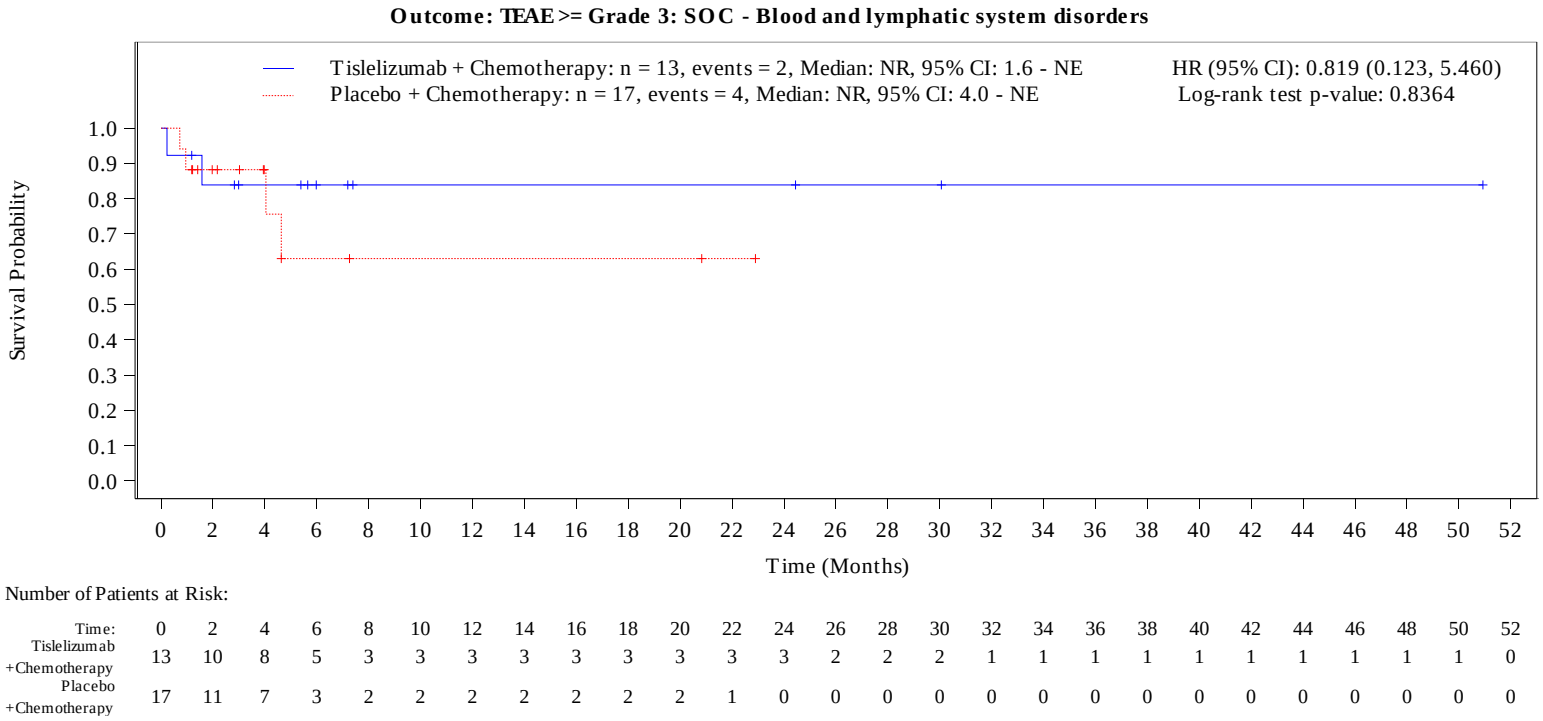


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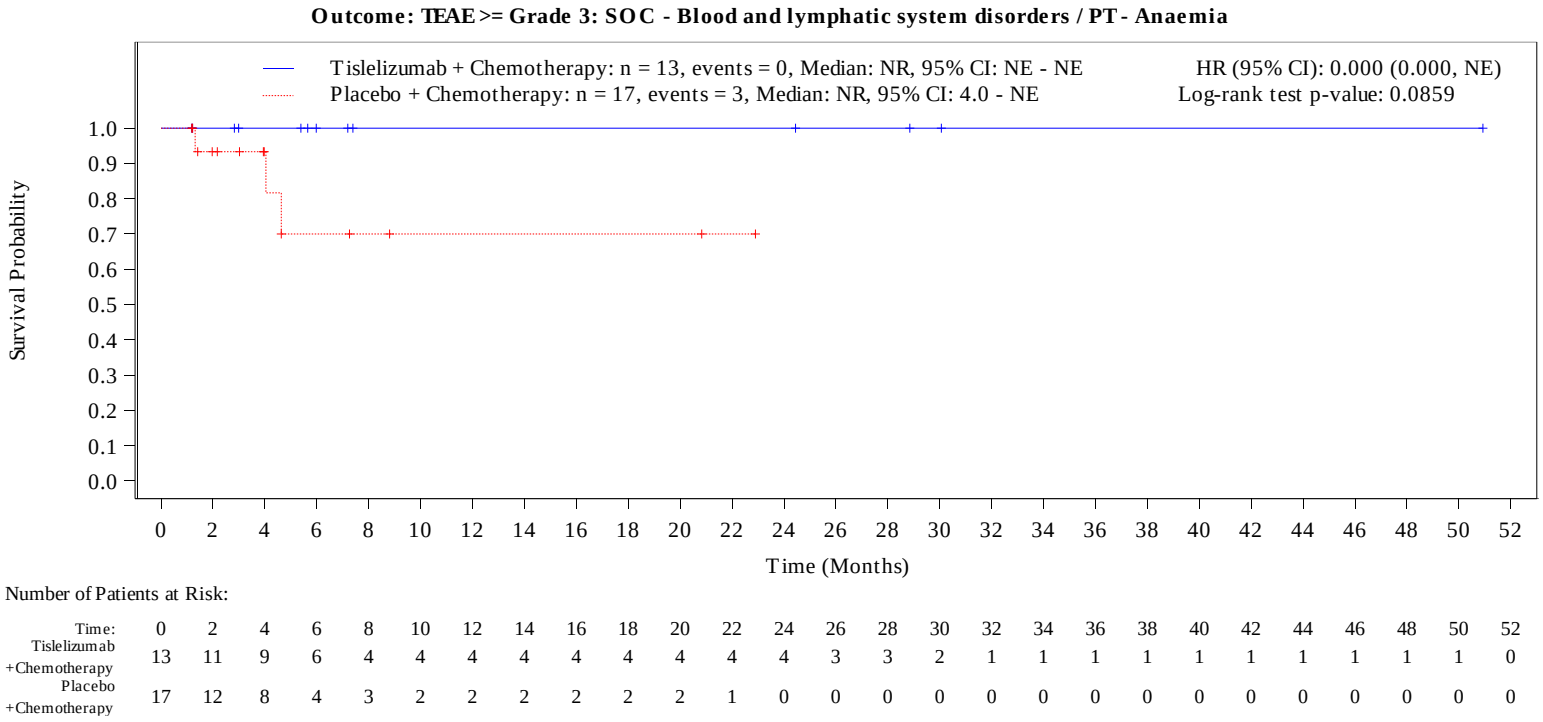
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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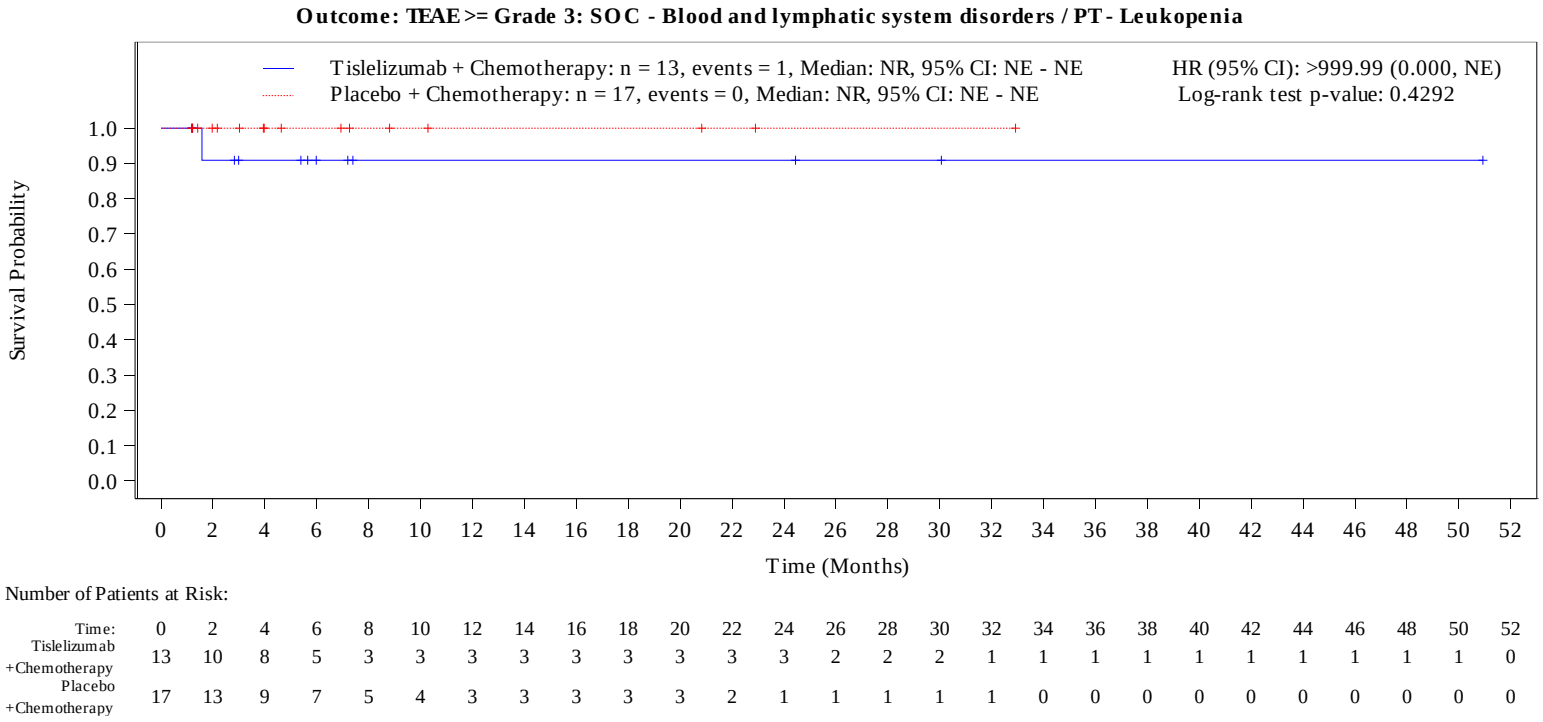

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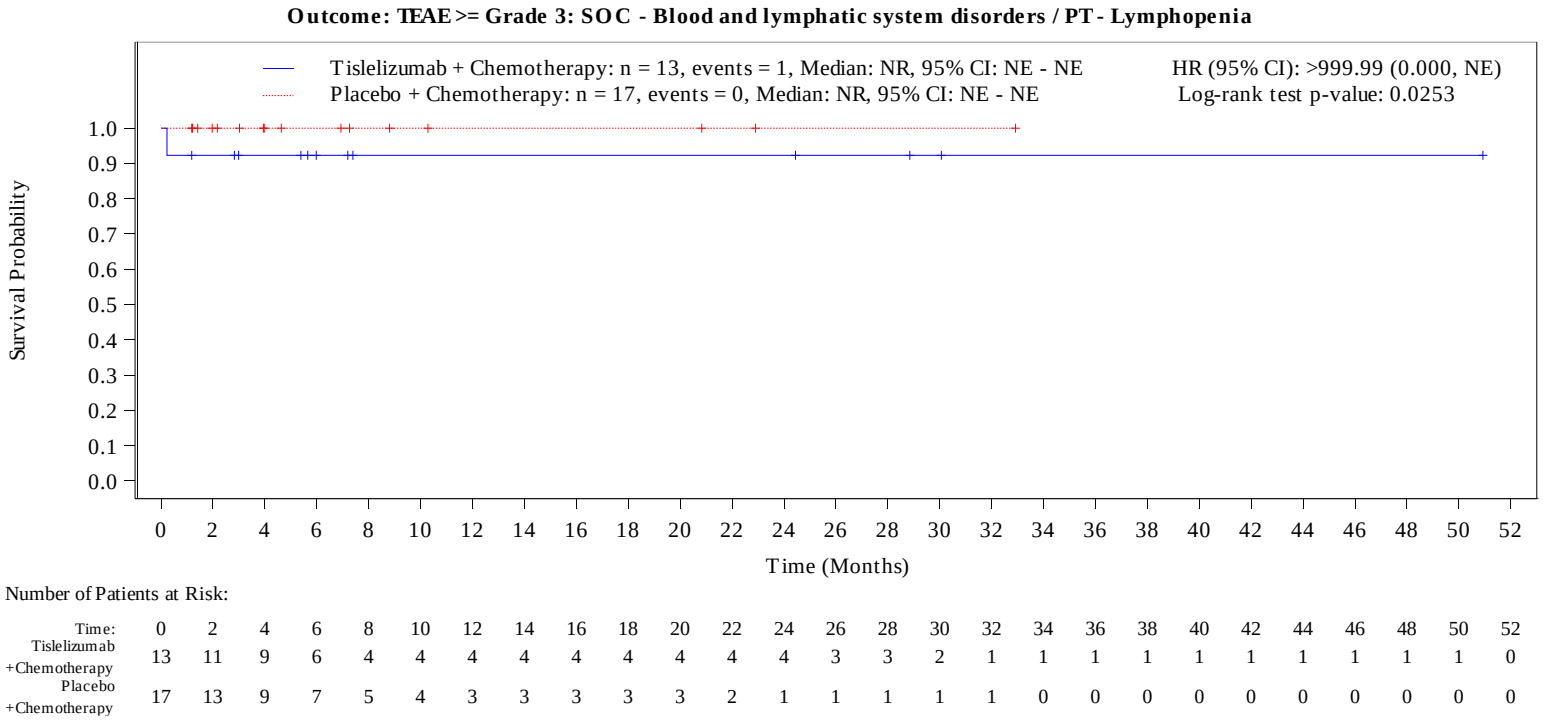

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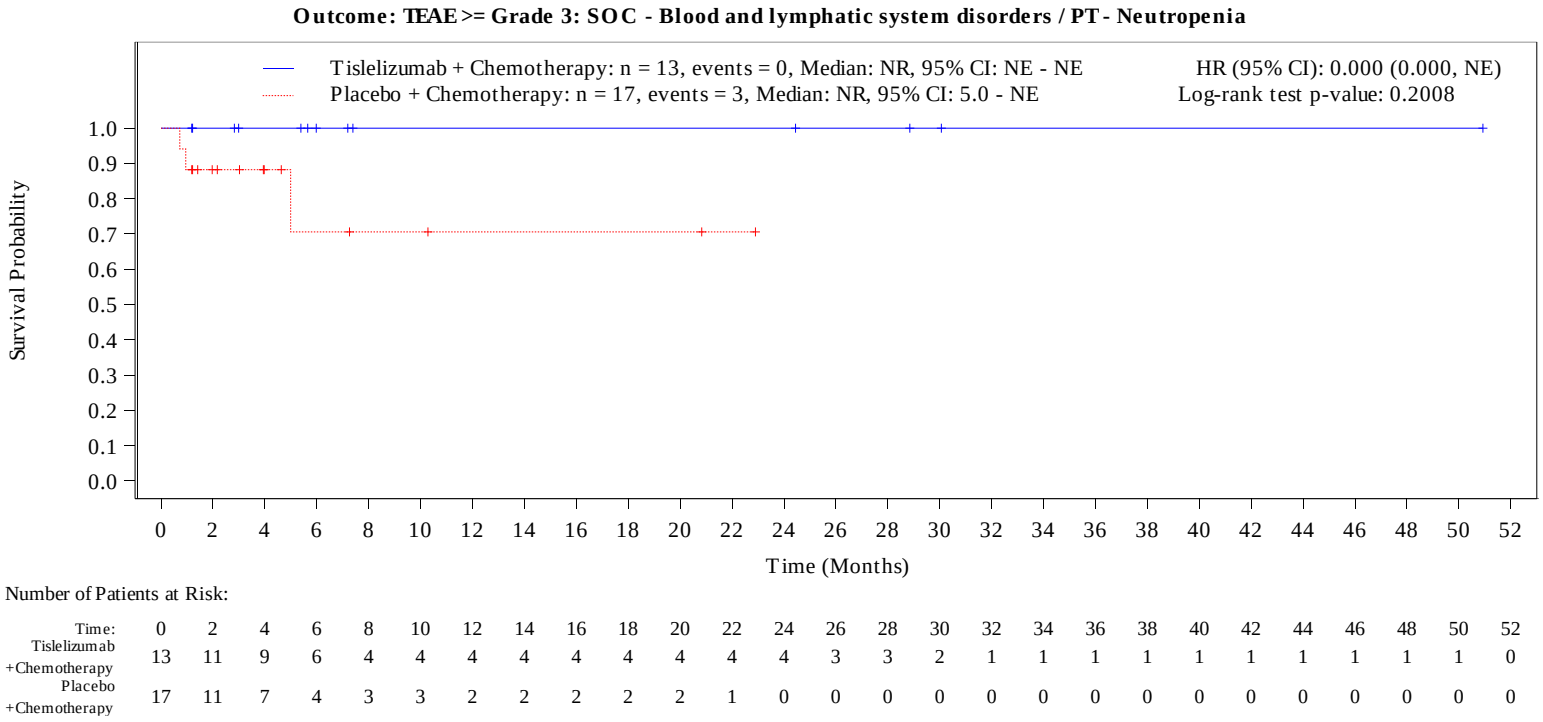

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	7	4	3	3	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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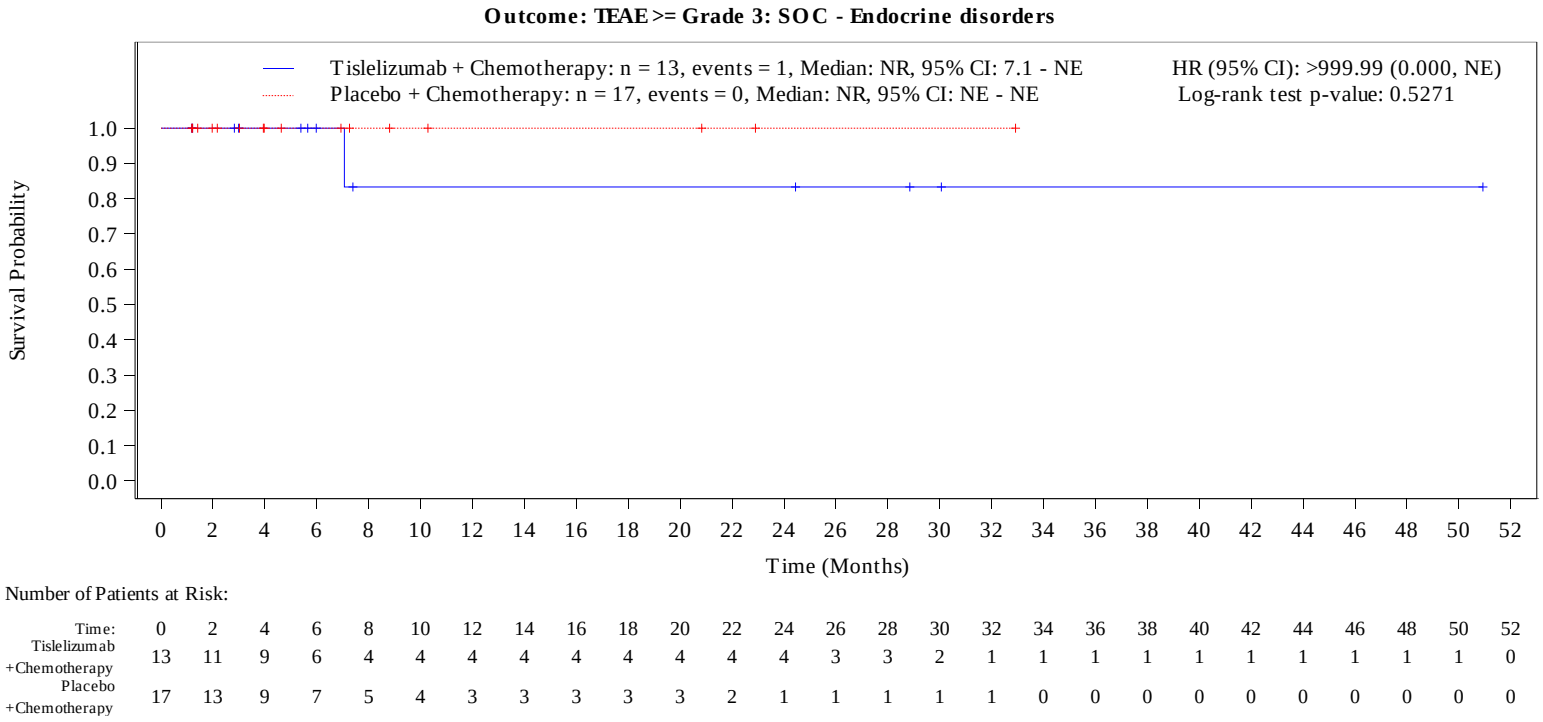
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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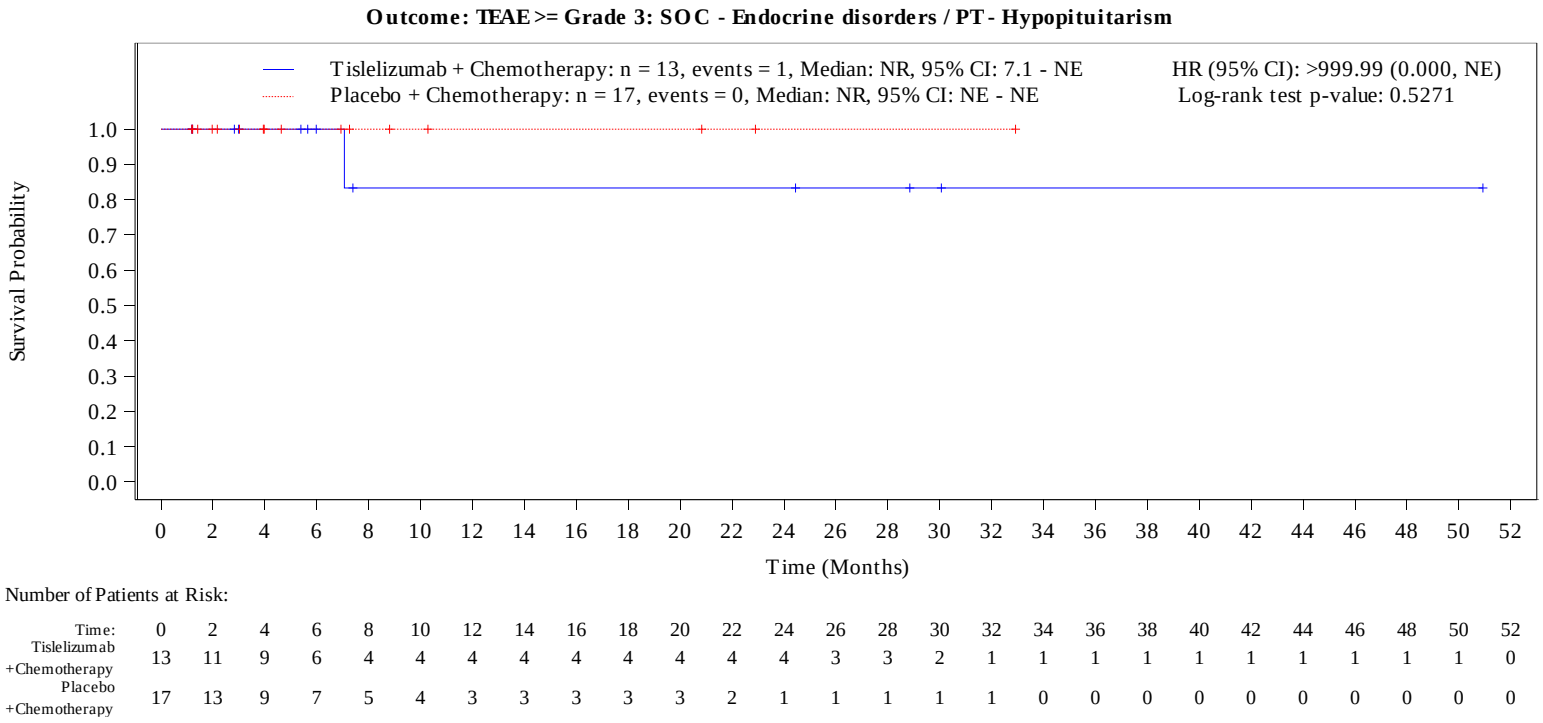

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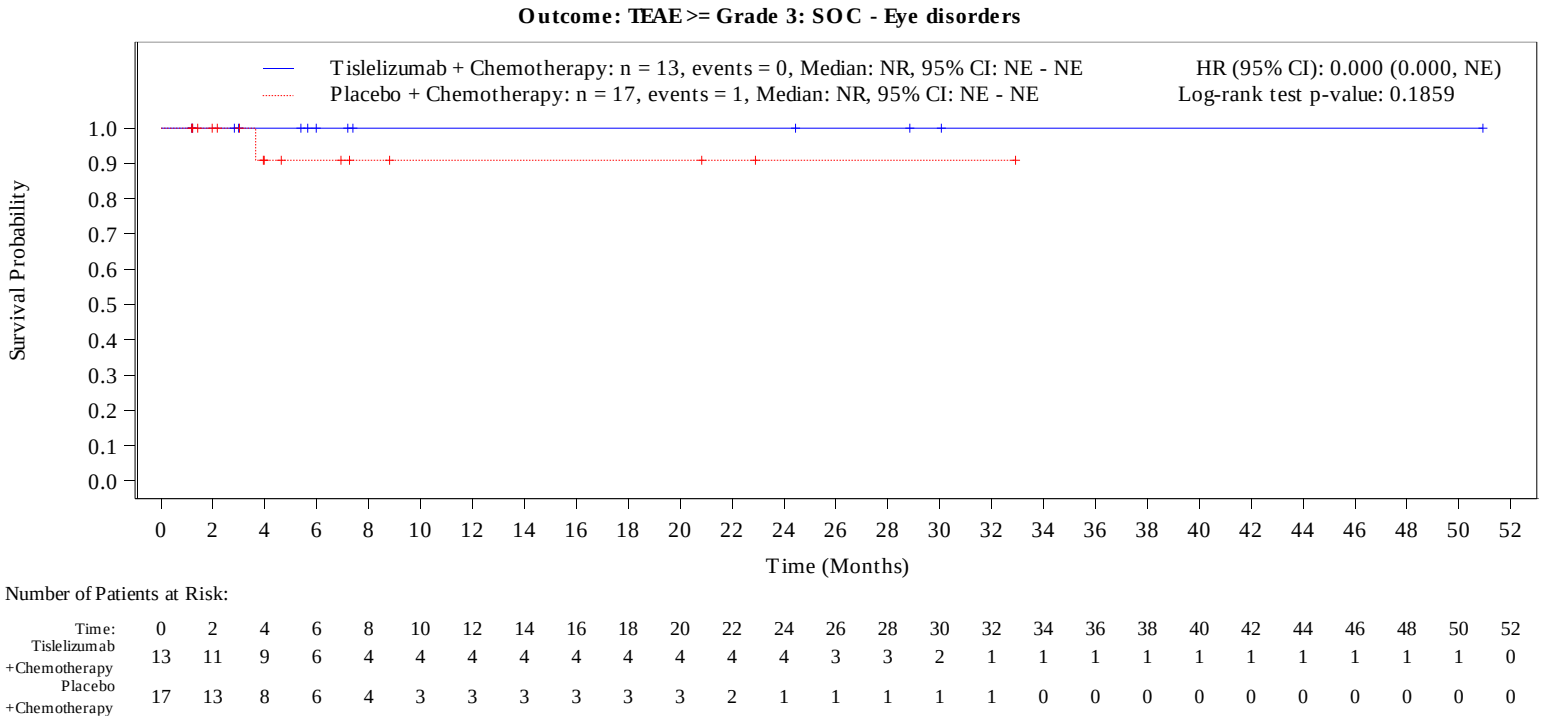

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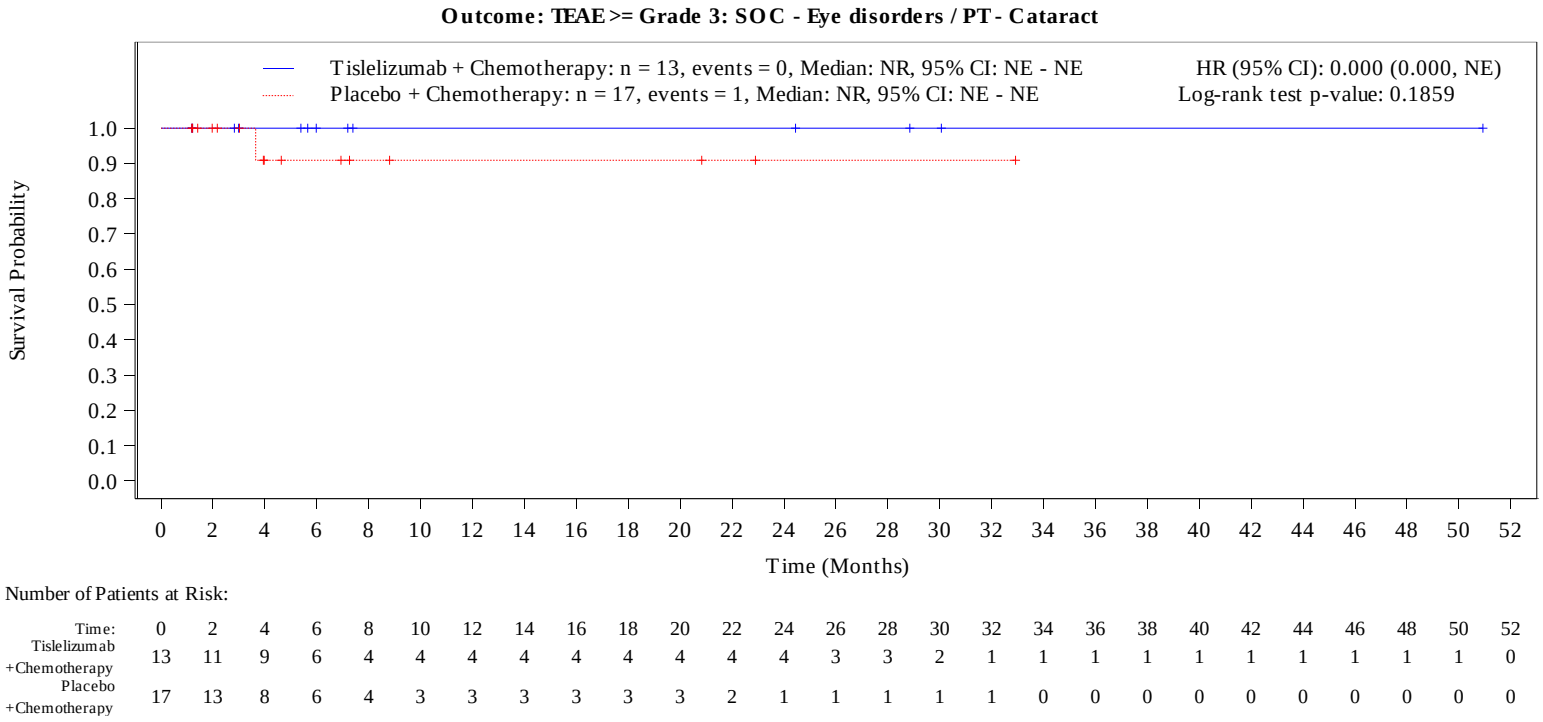

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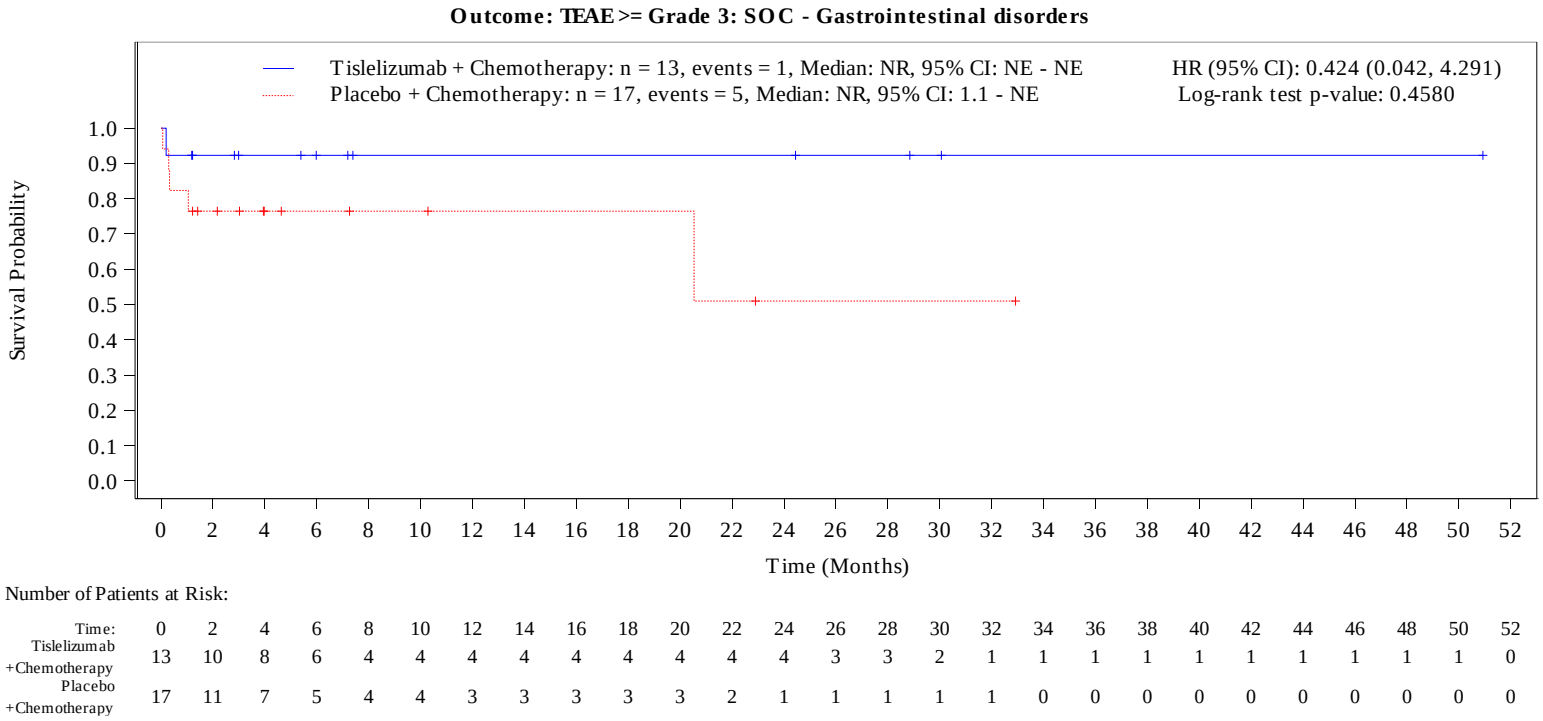

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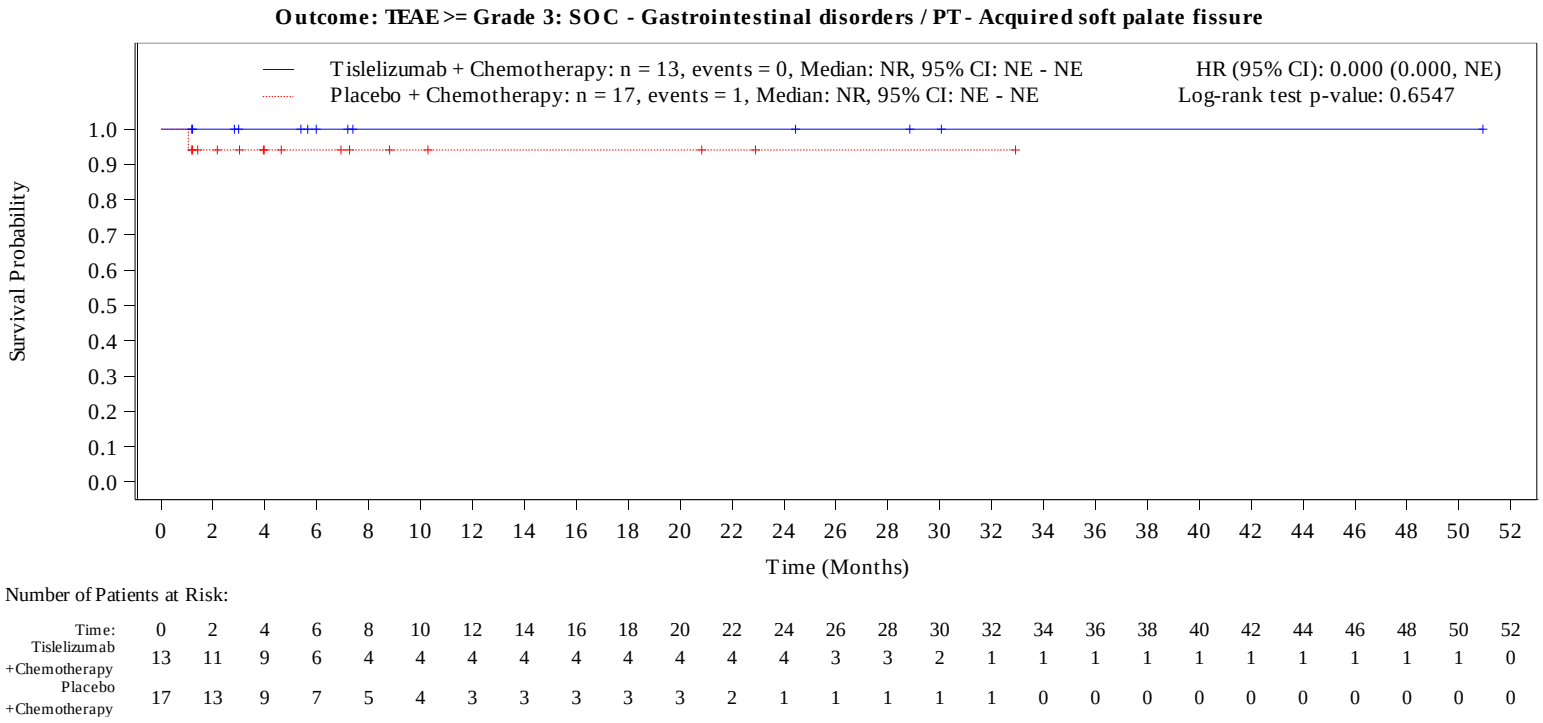

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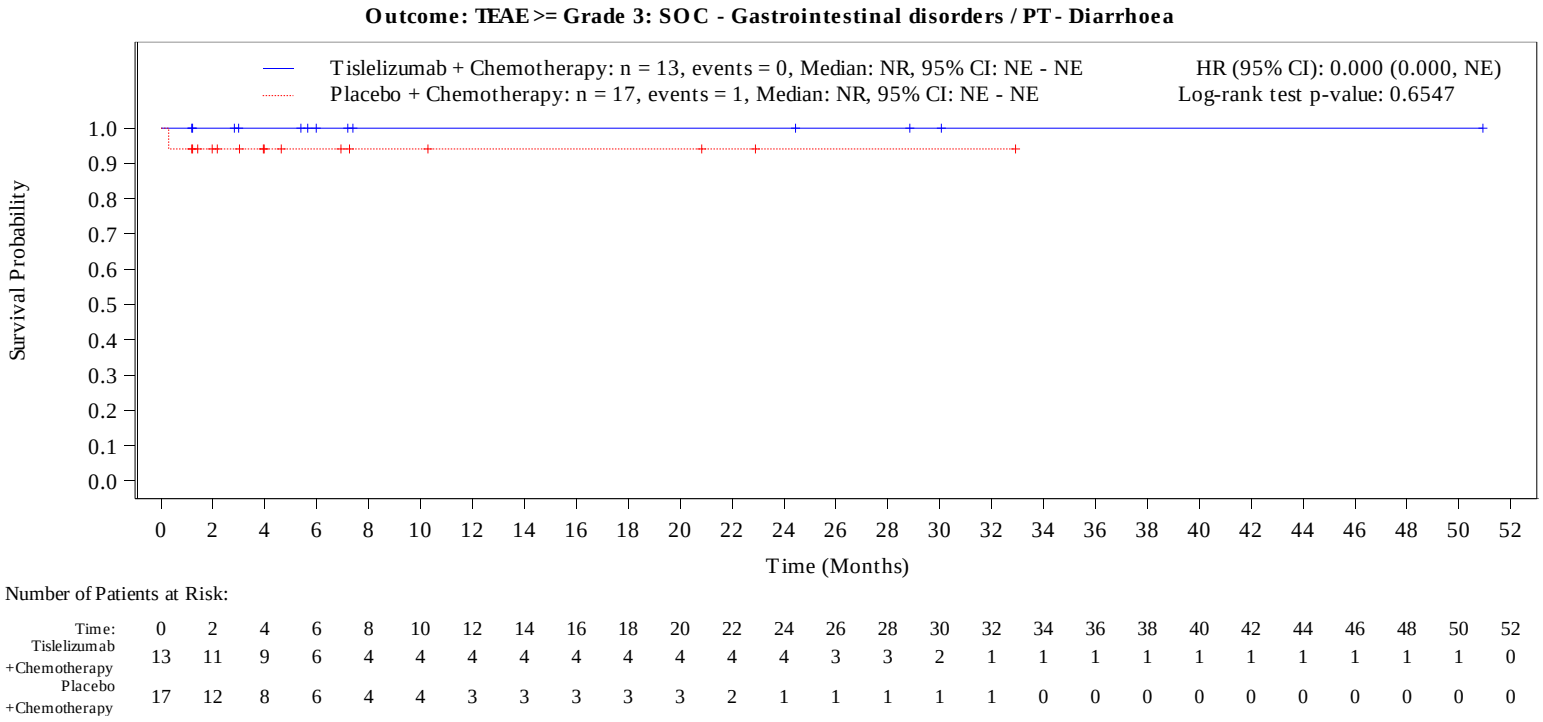

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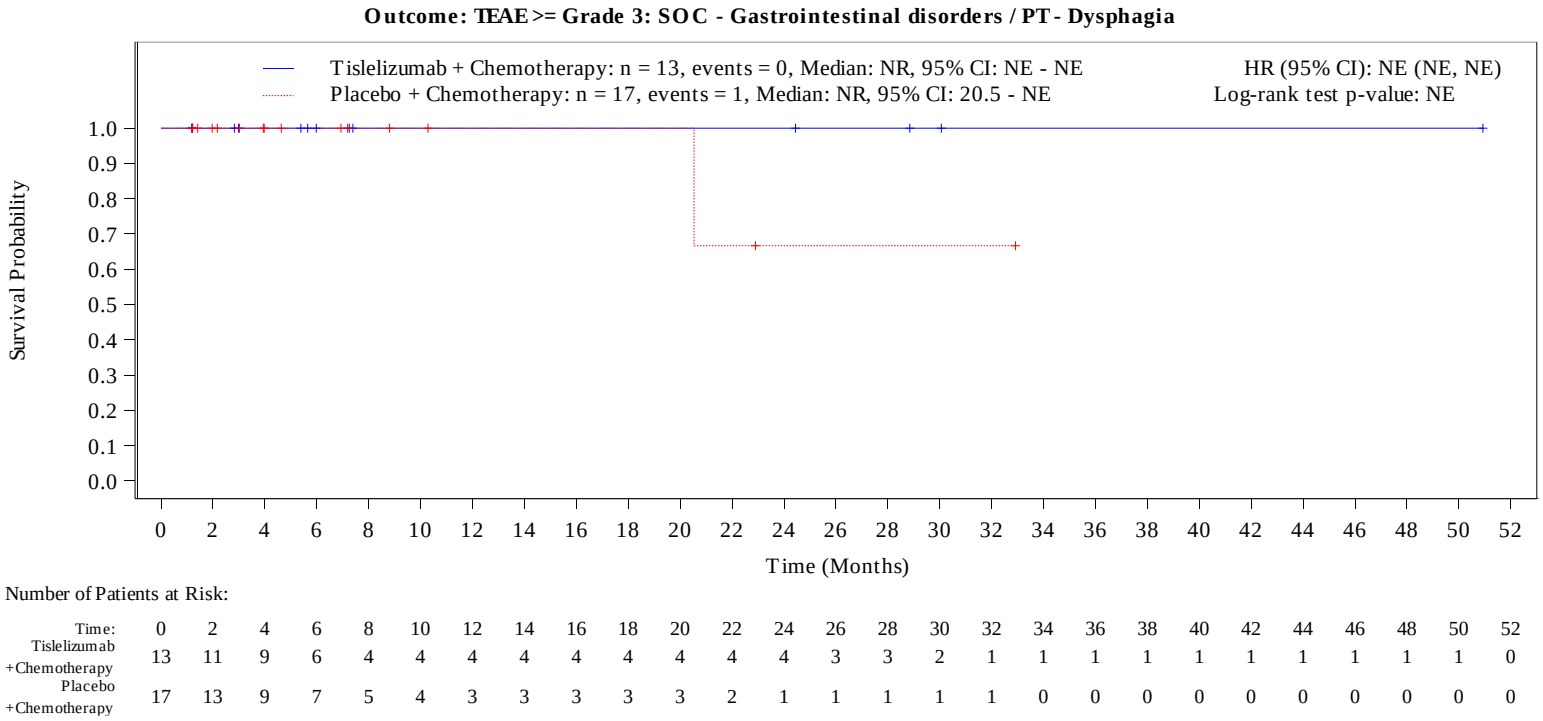

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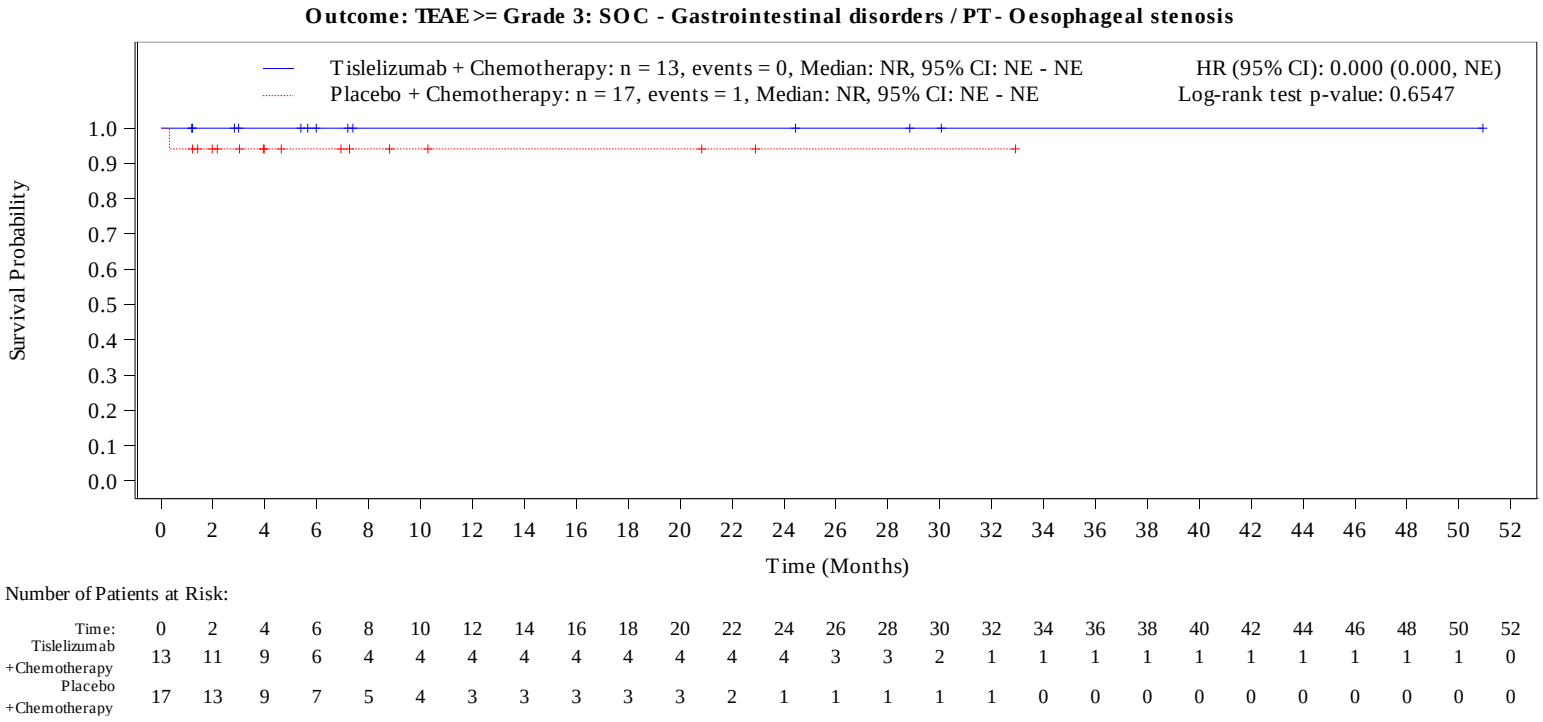

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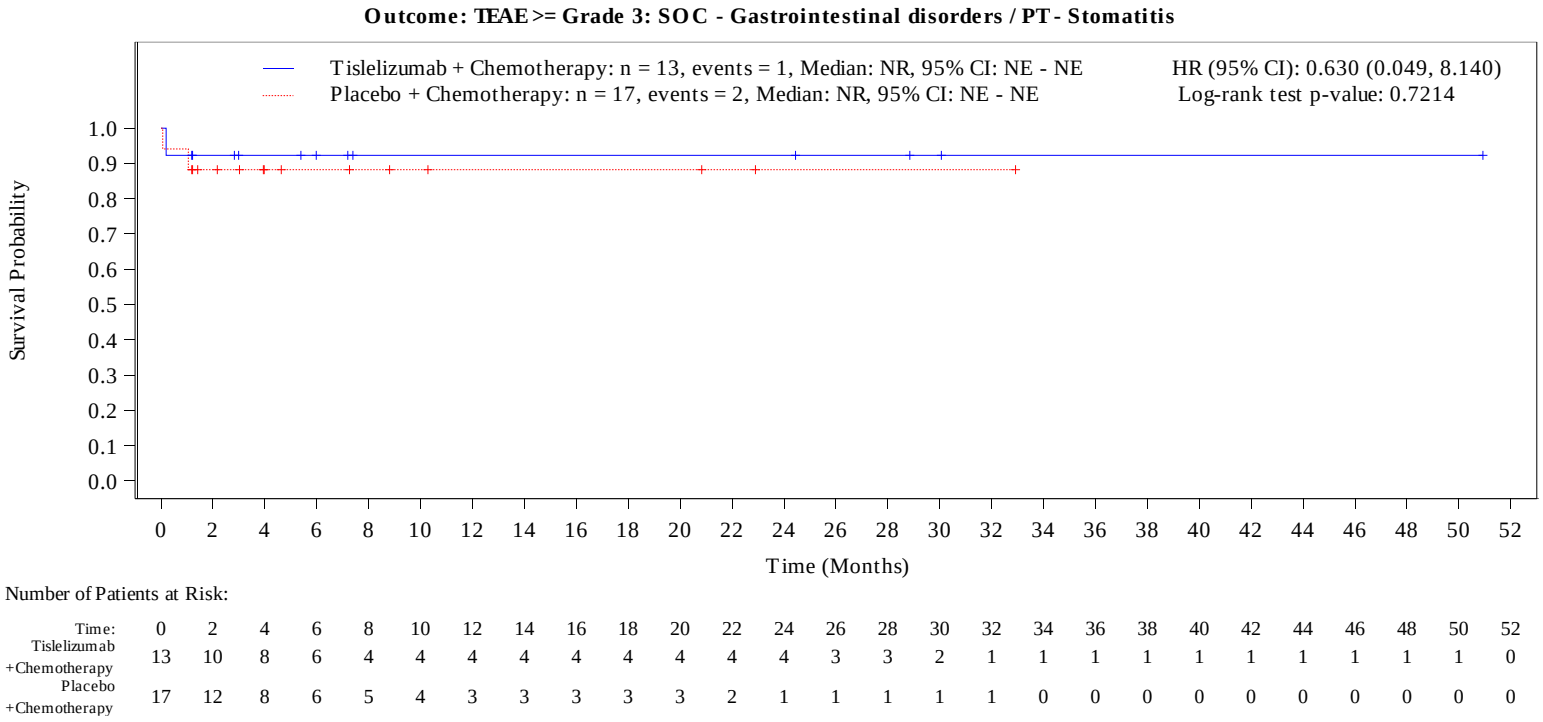

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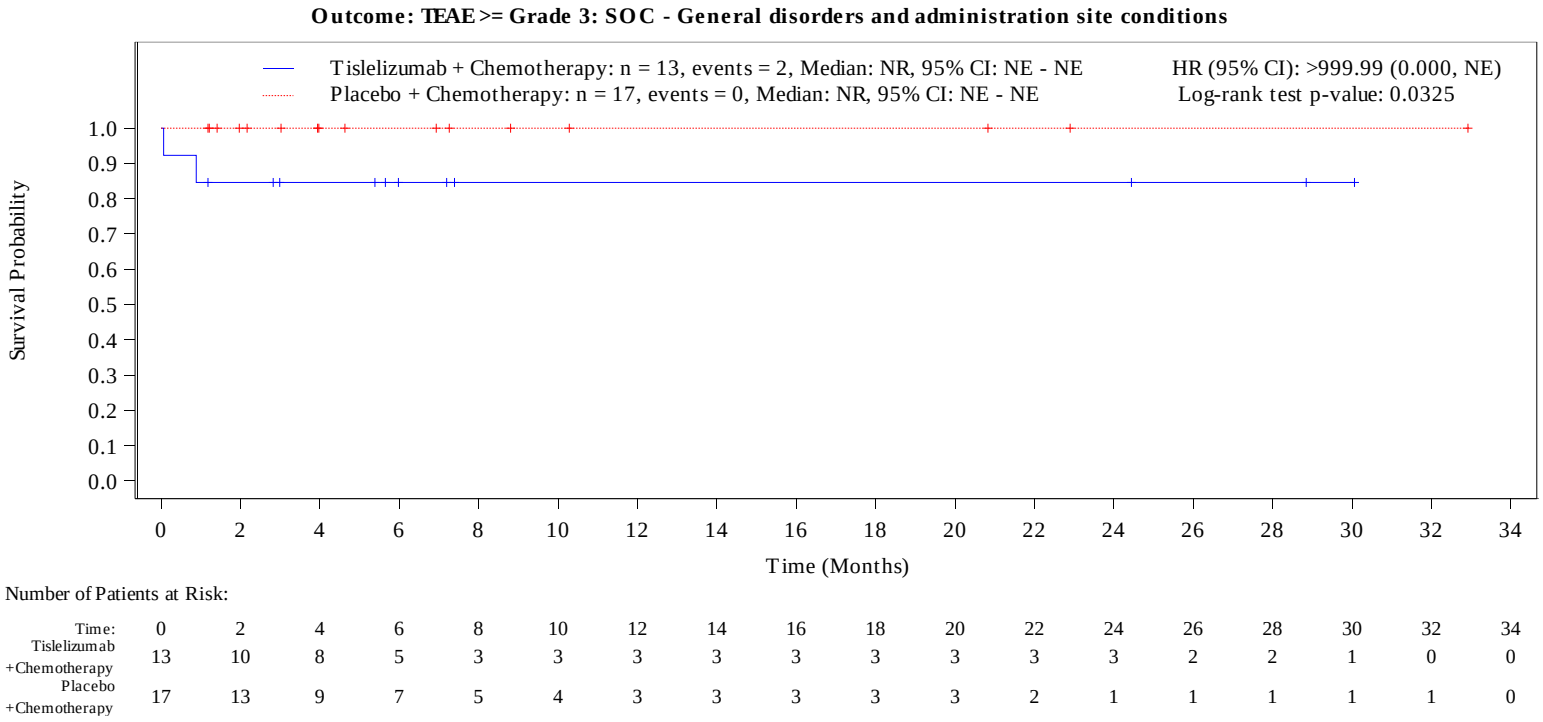

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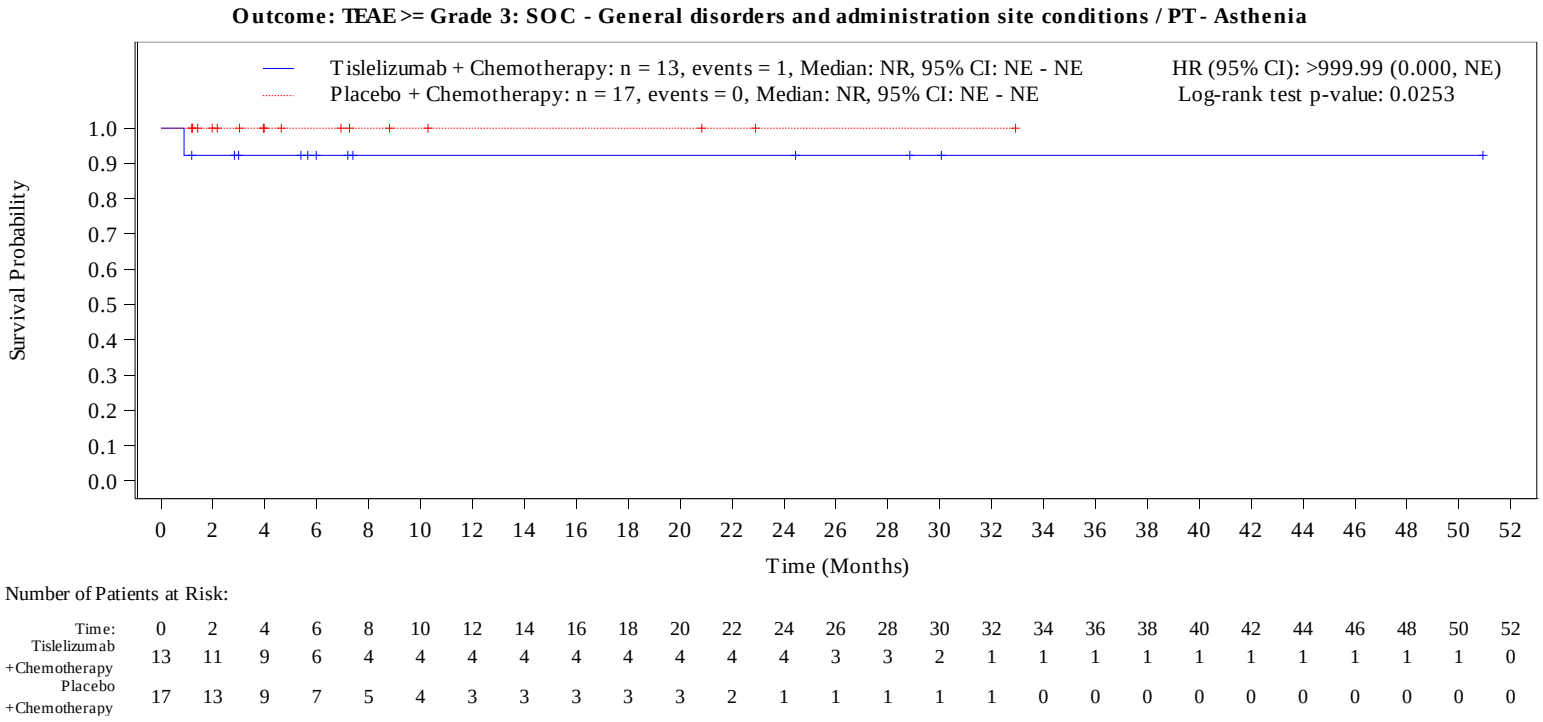

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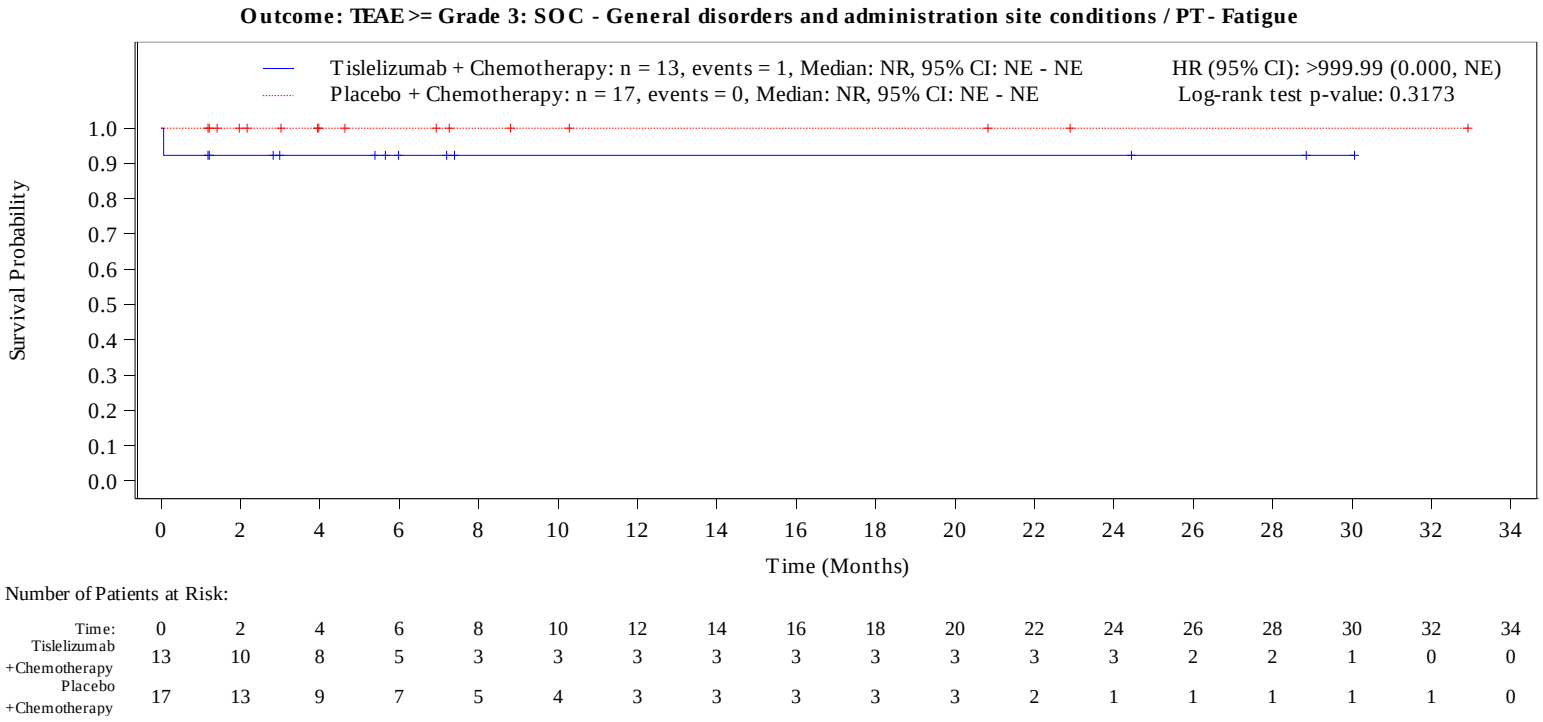

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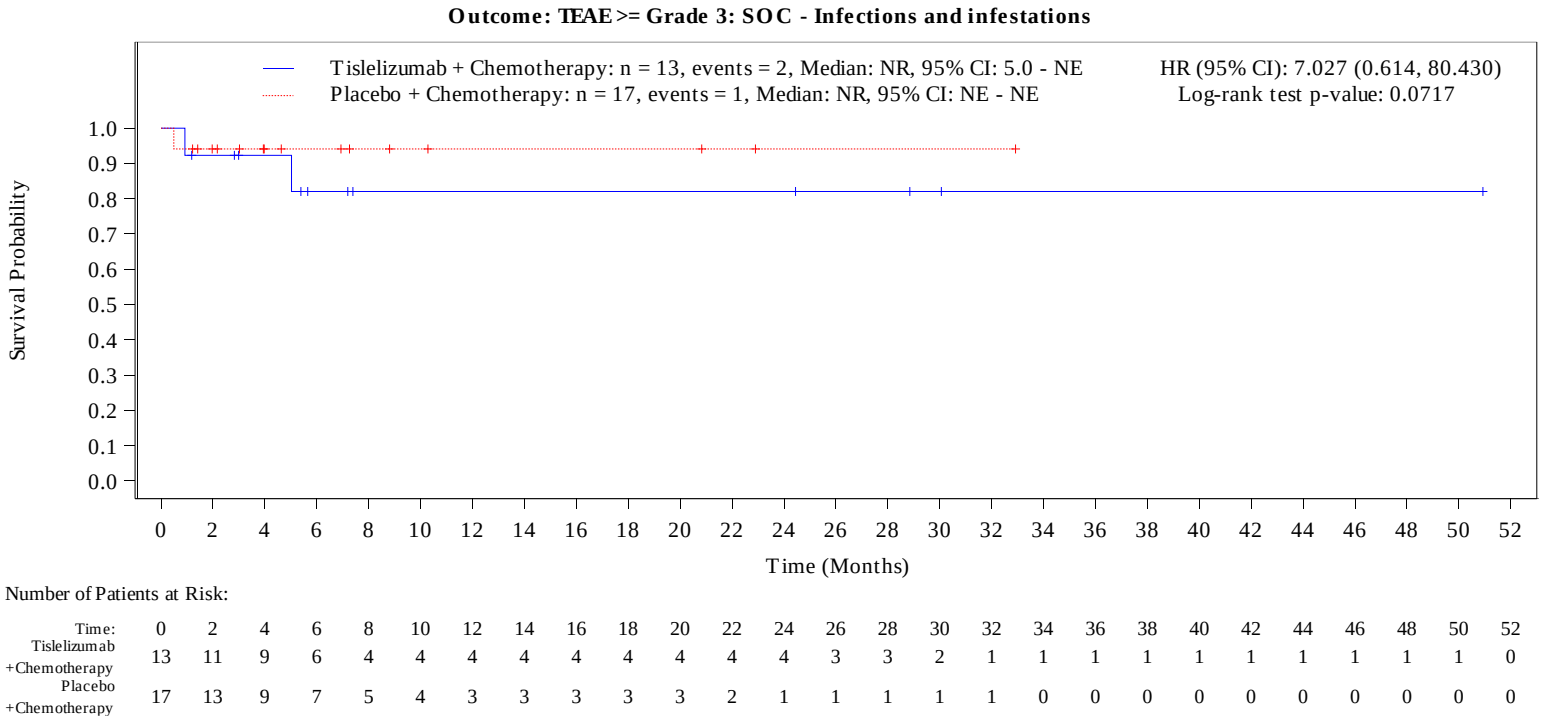

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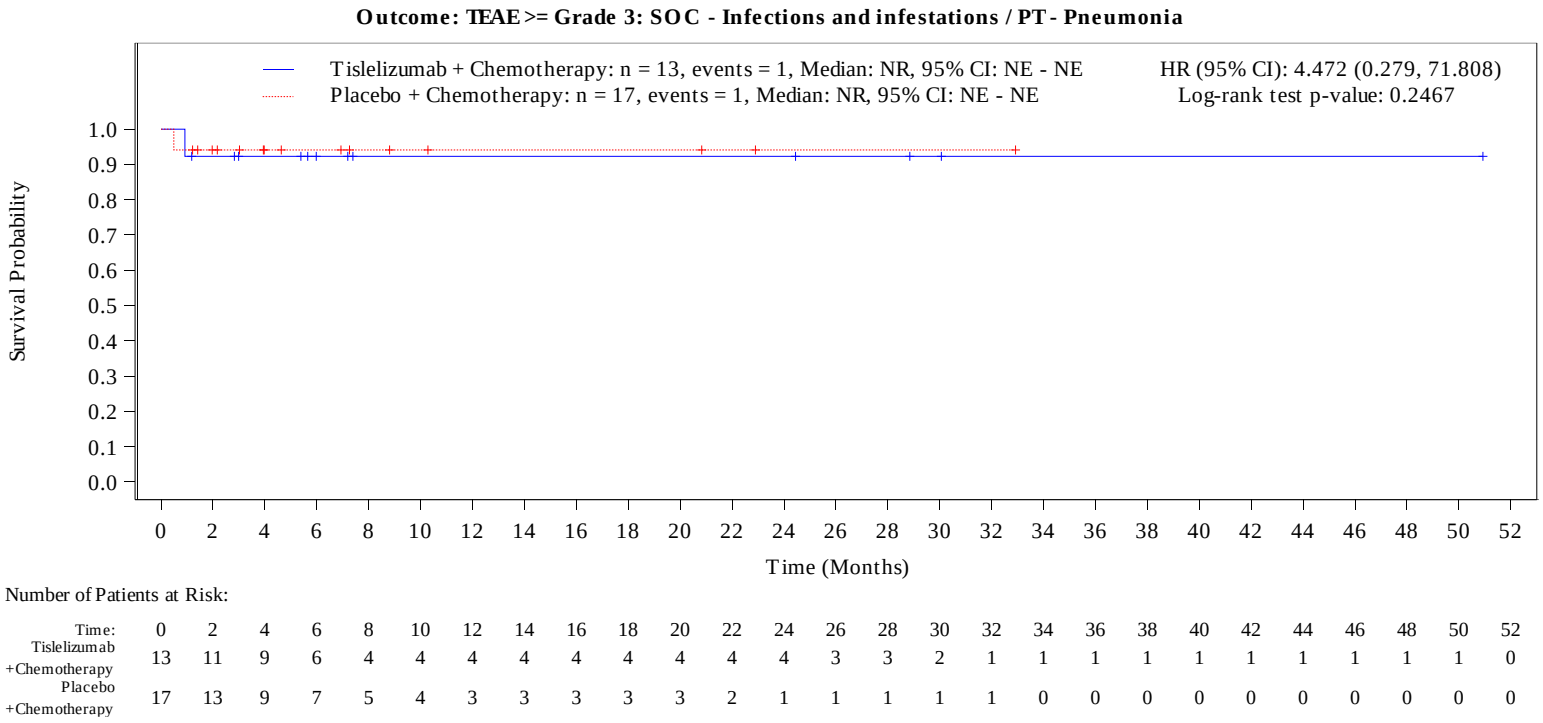

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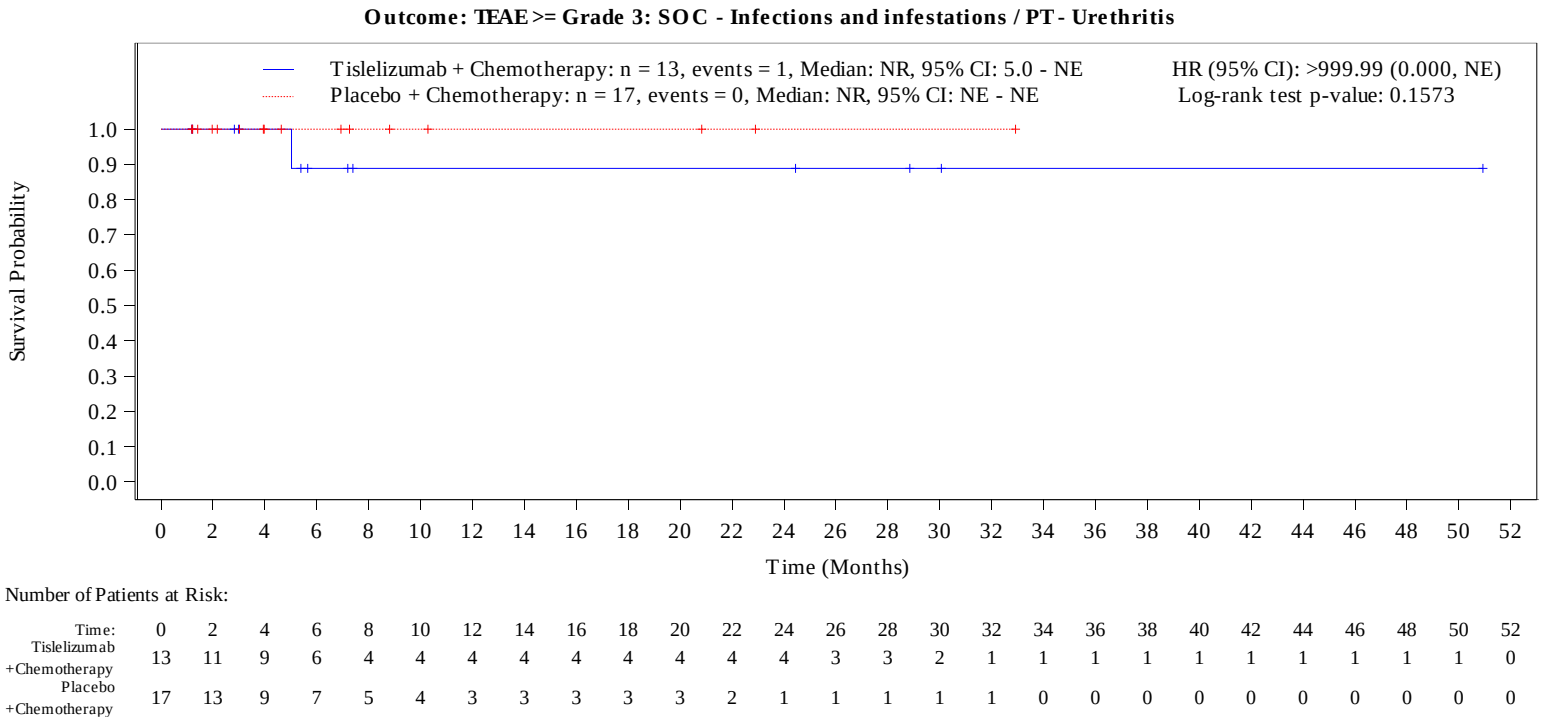
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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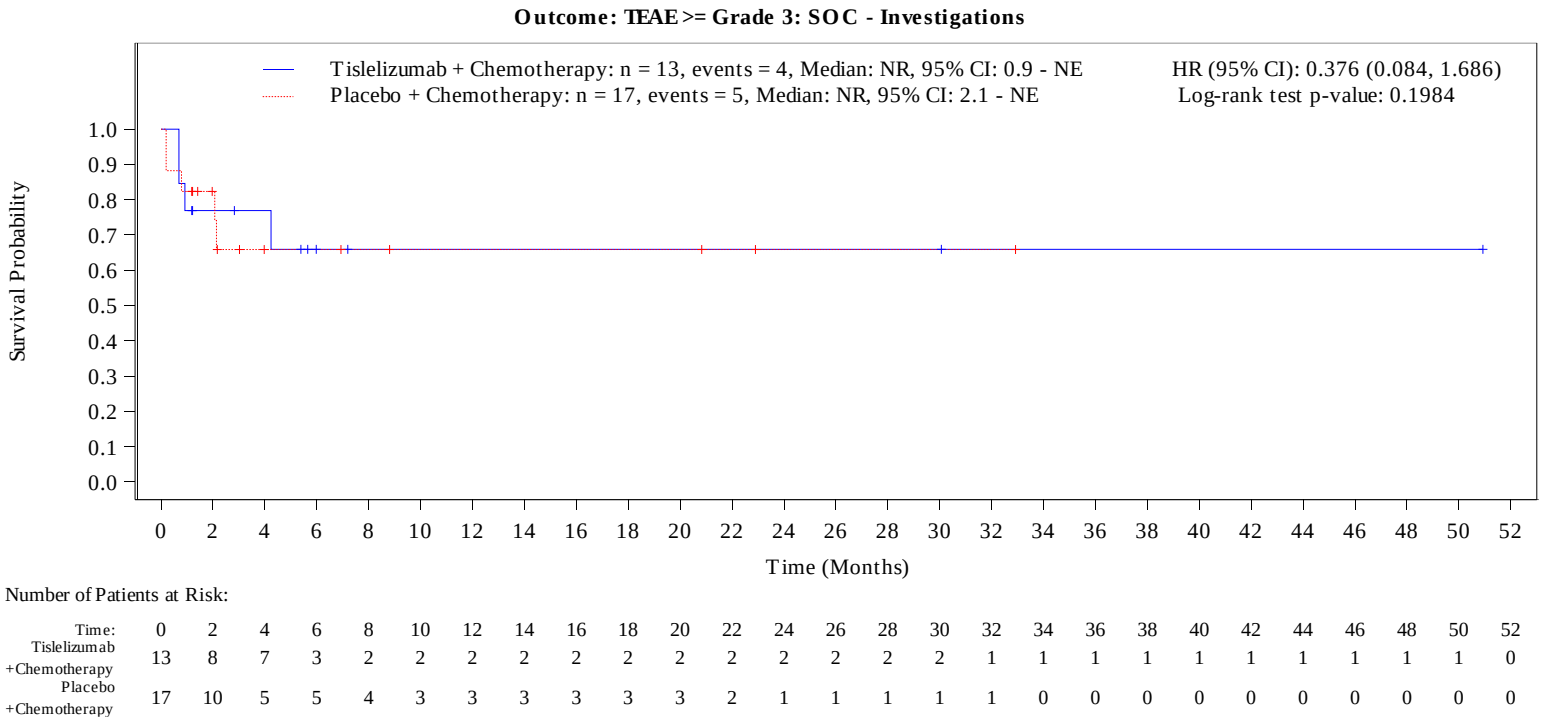

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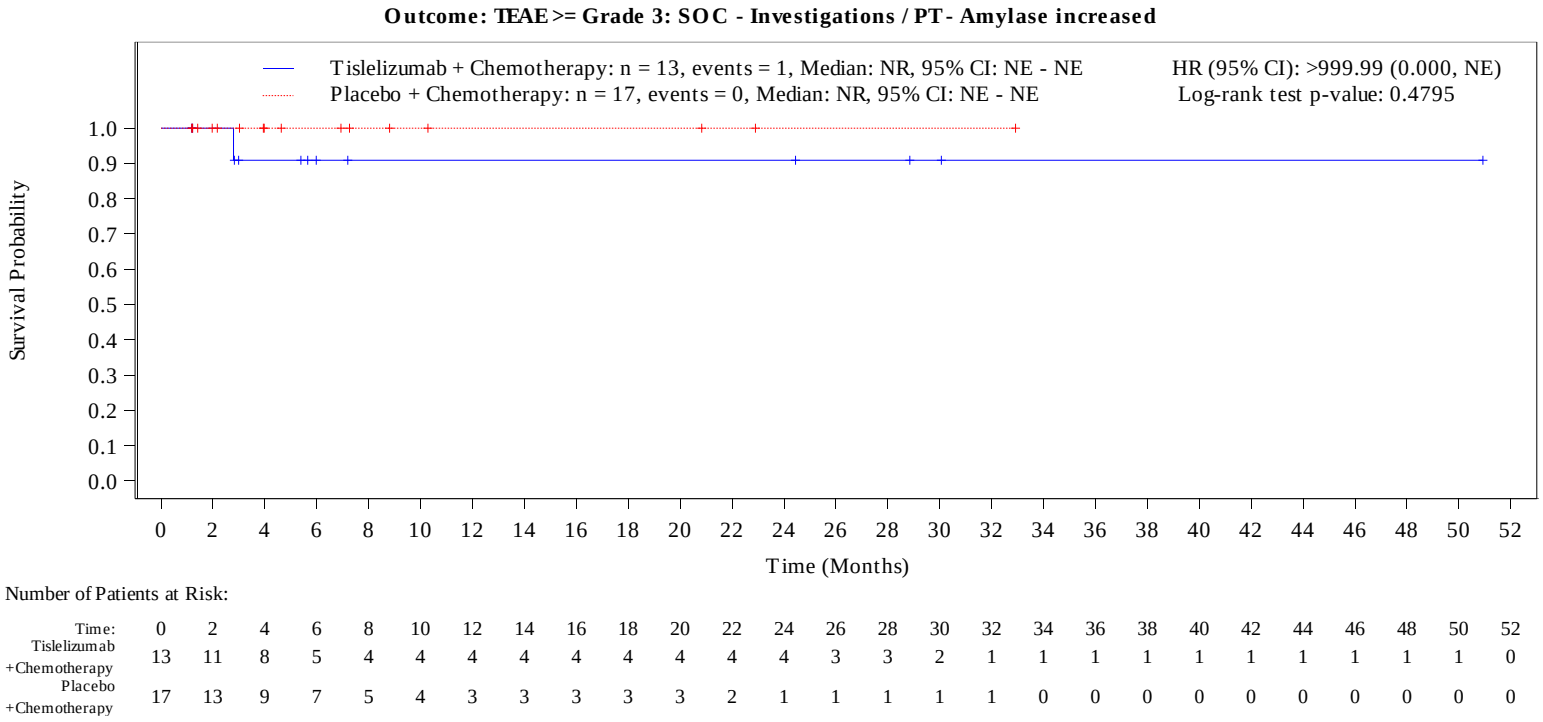

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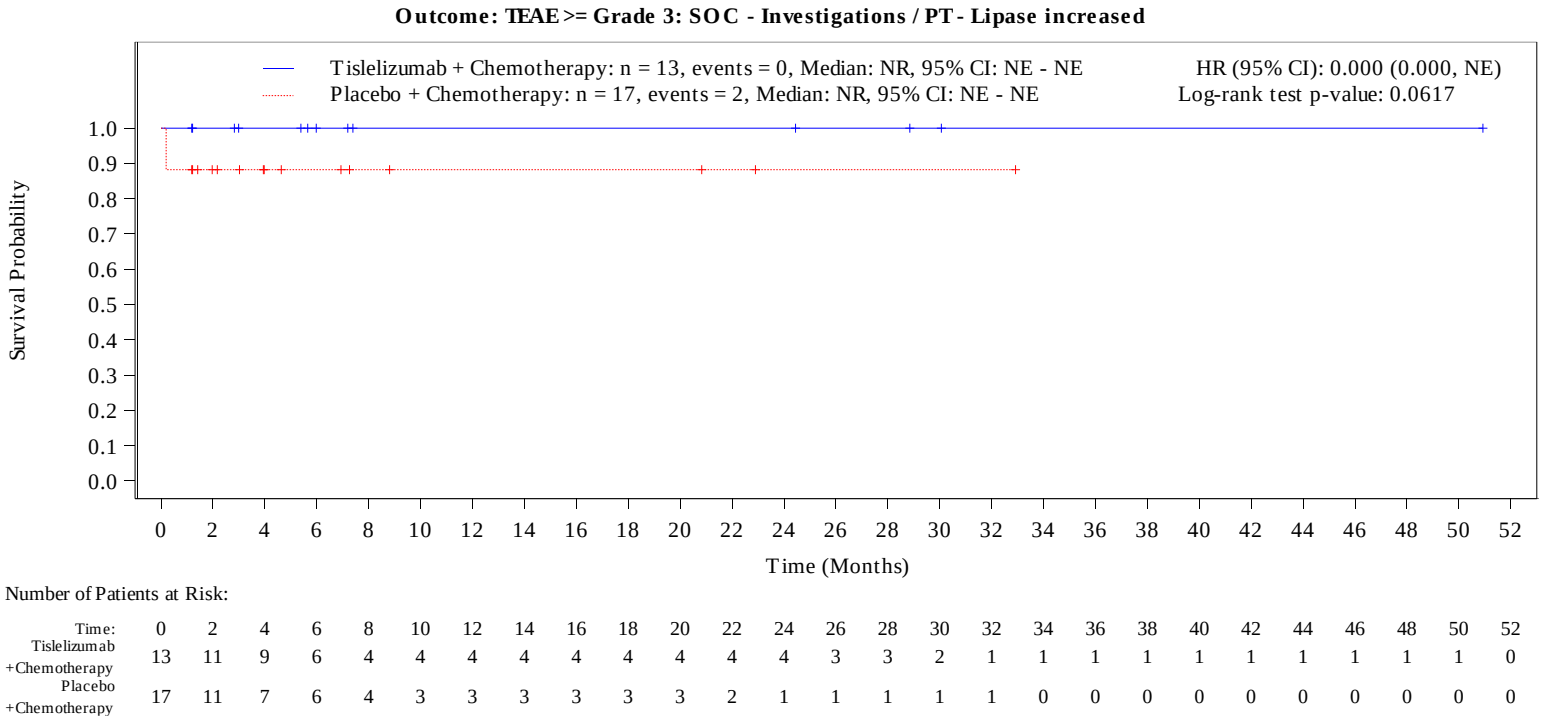

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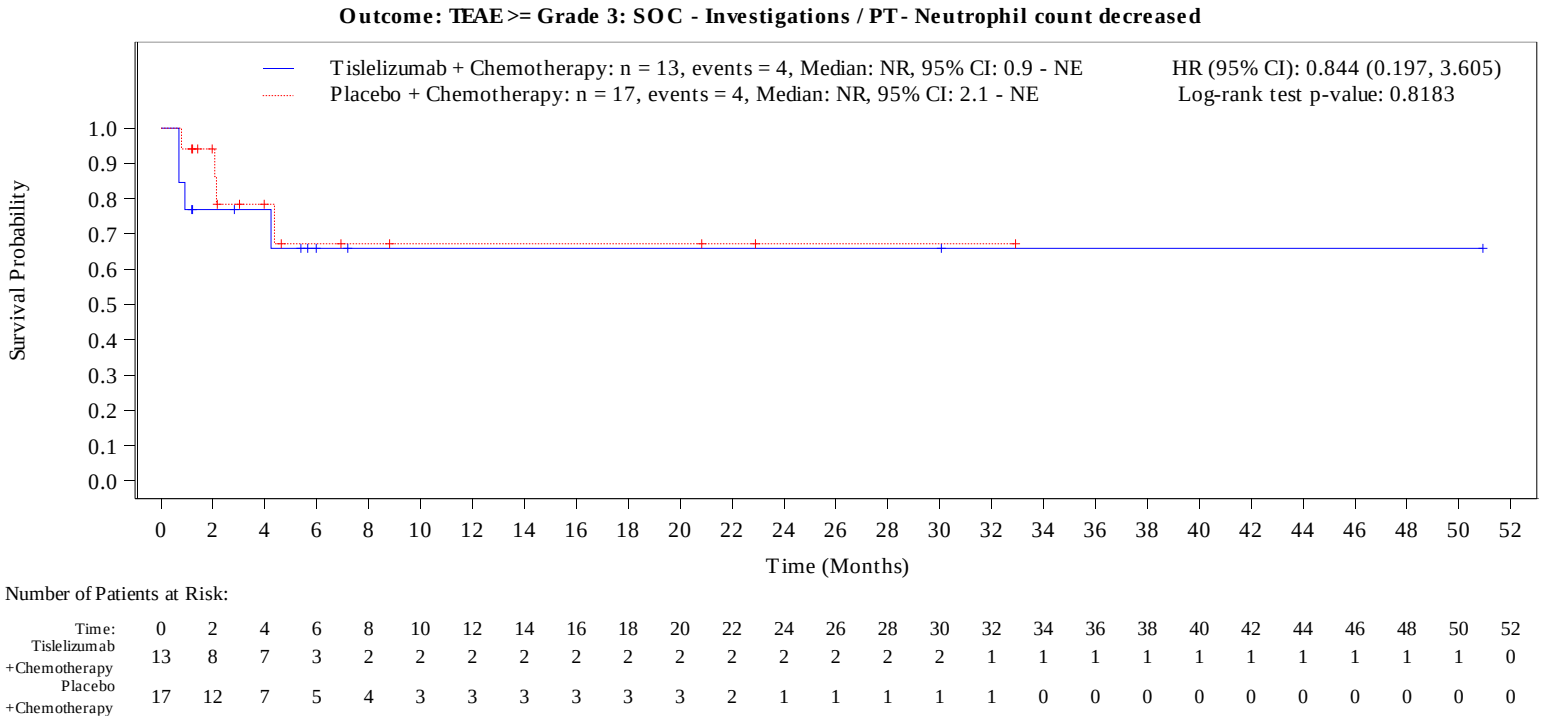

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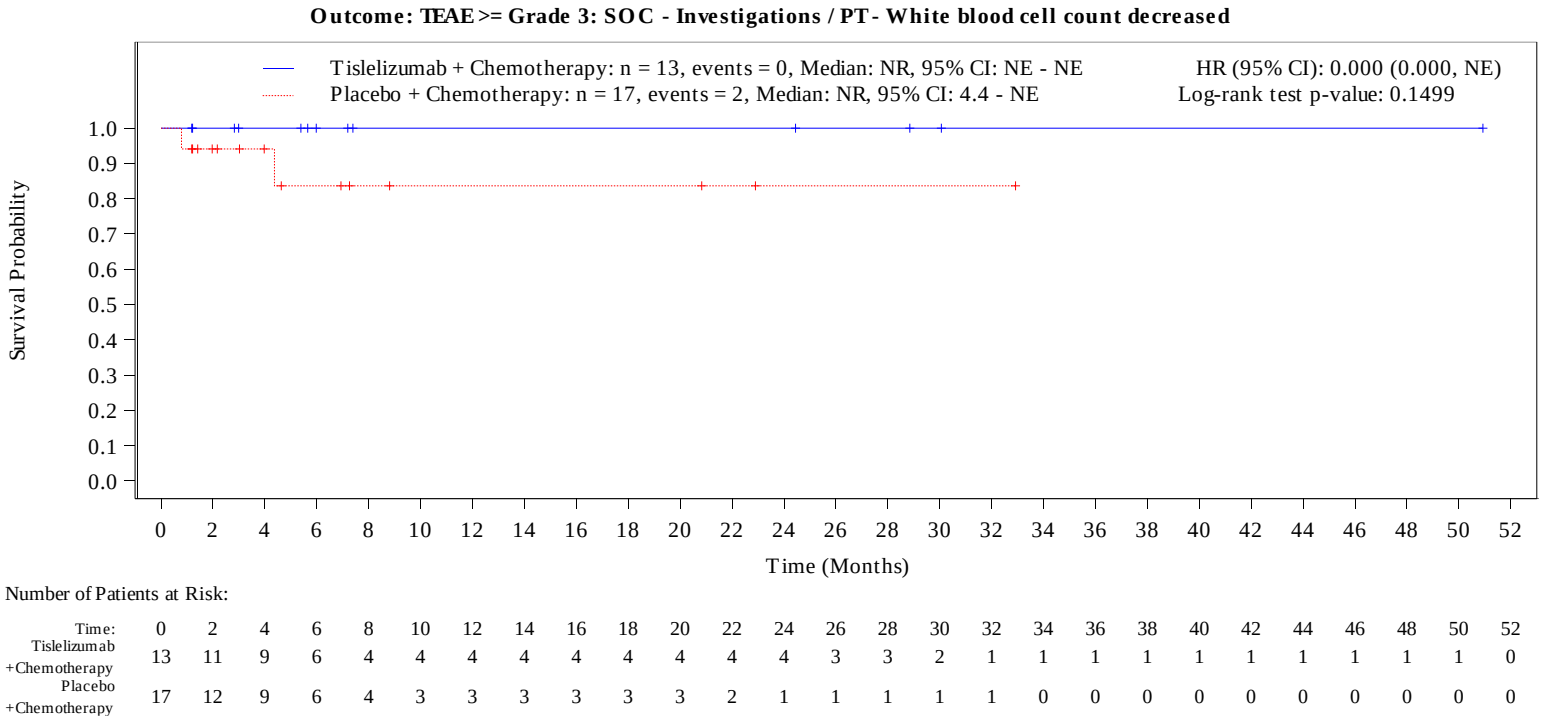

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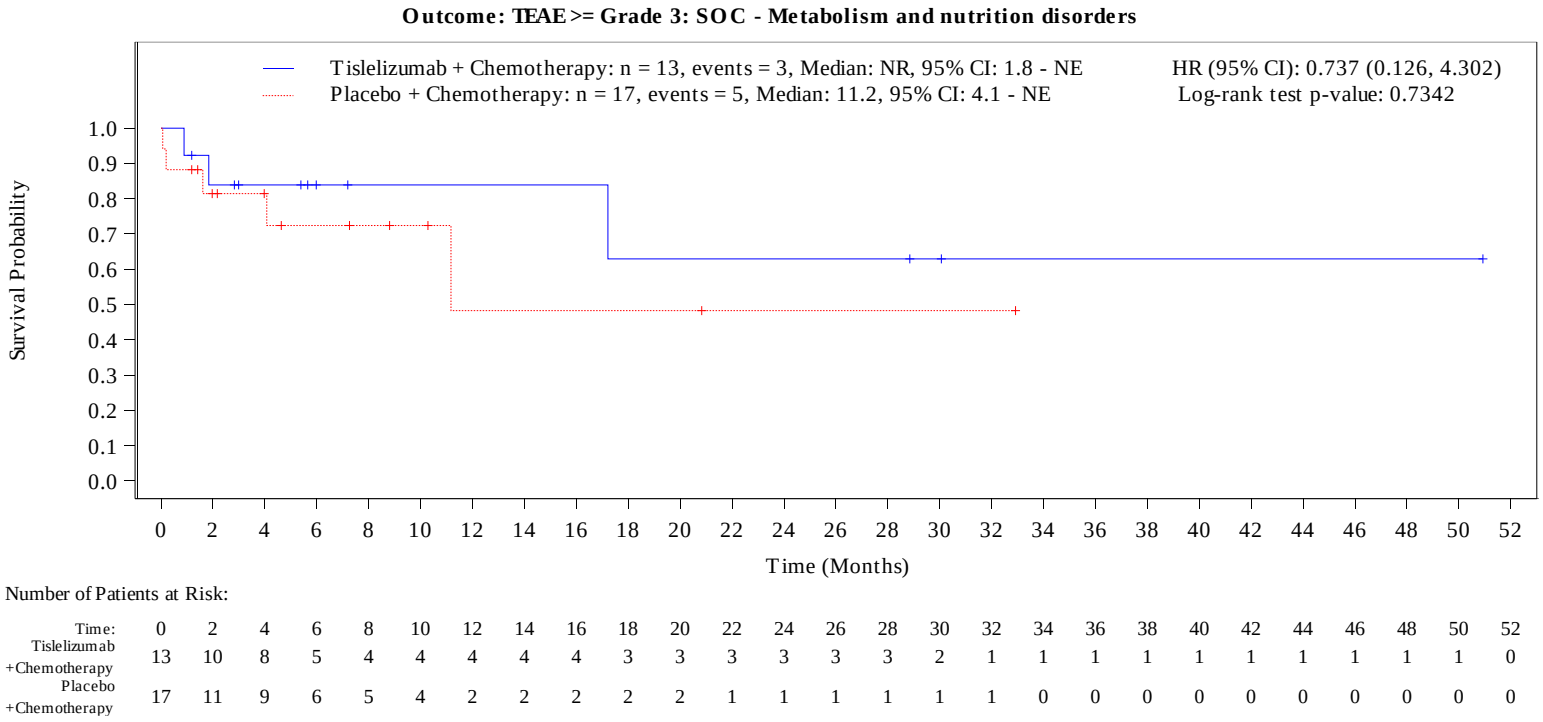

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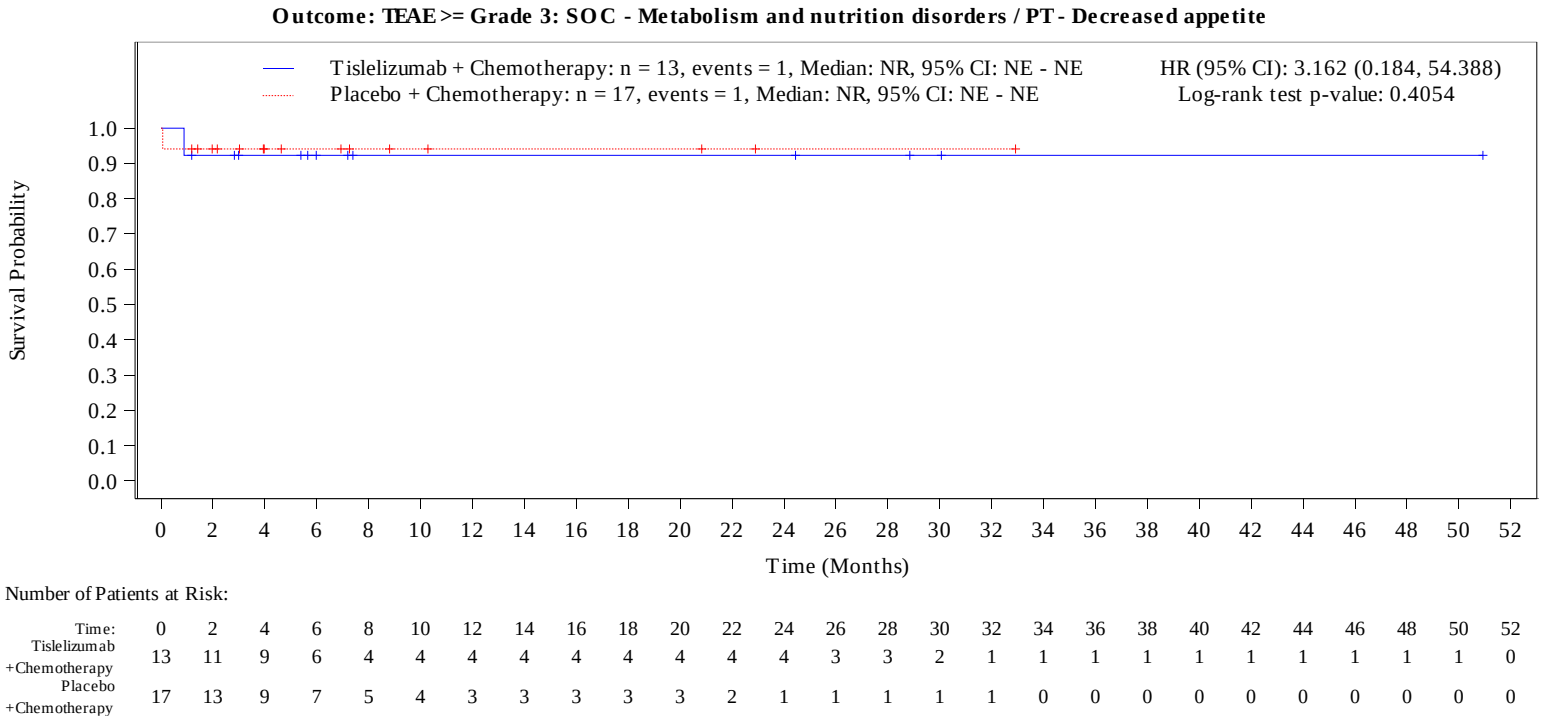

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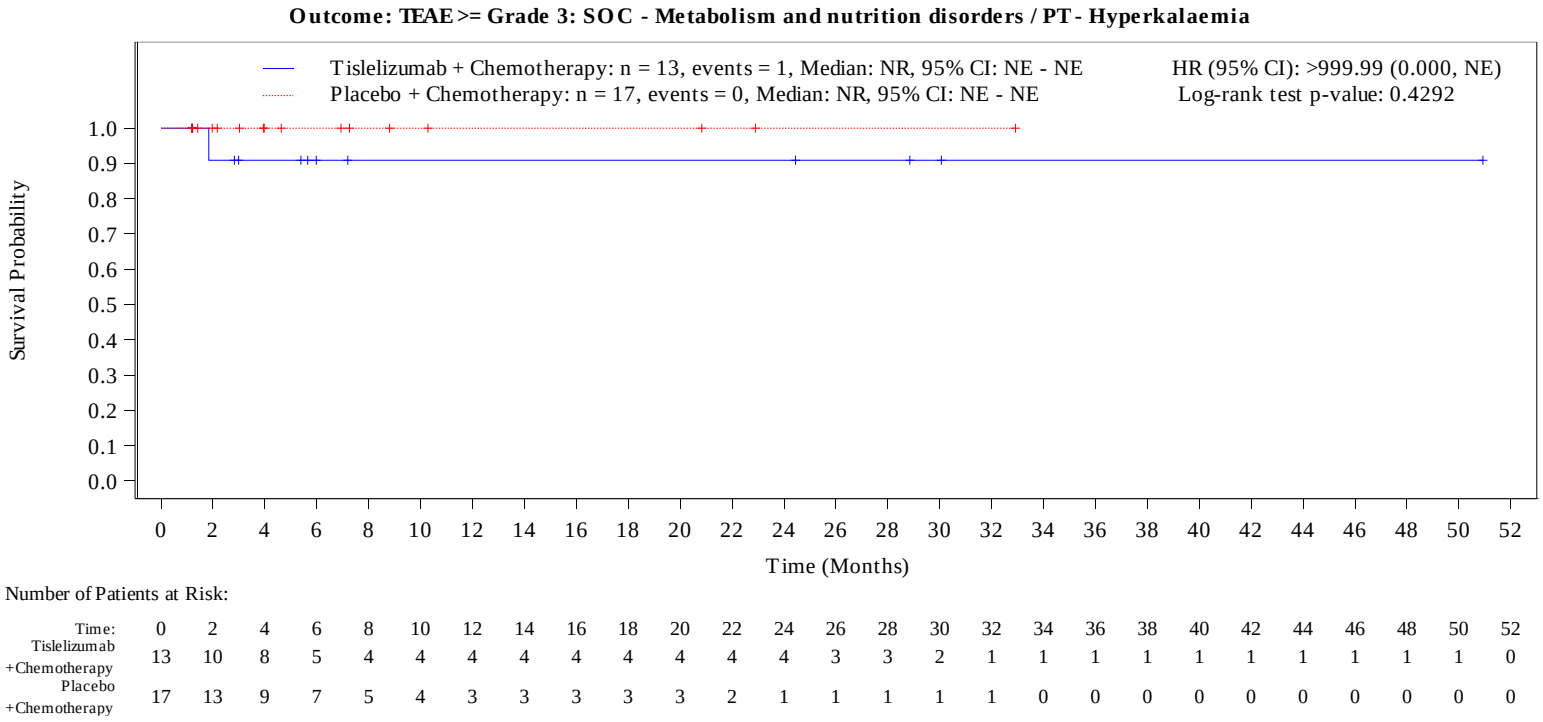

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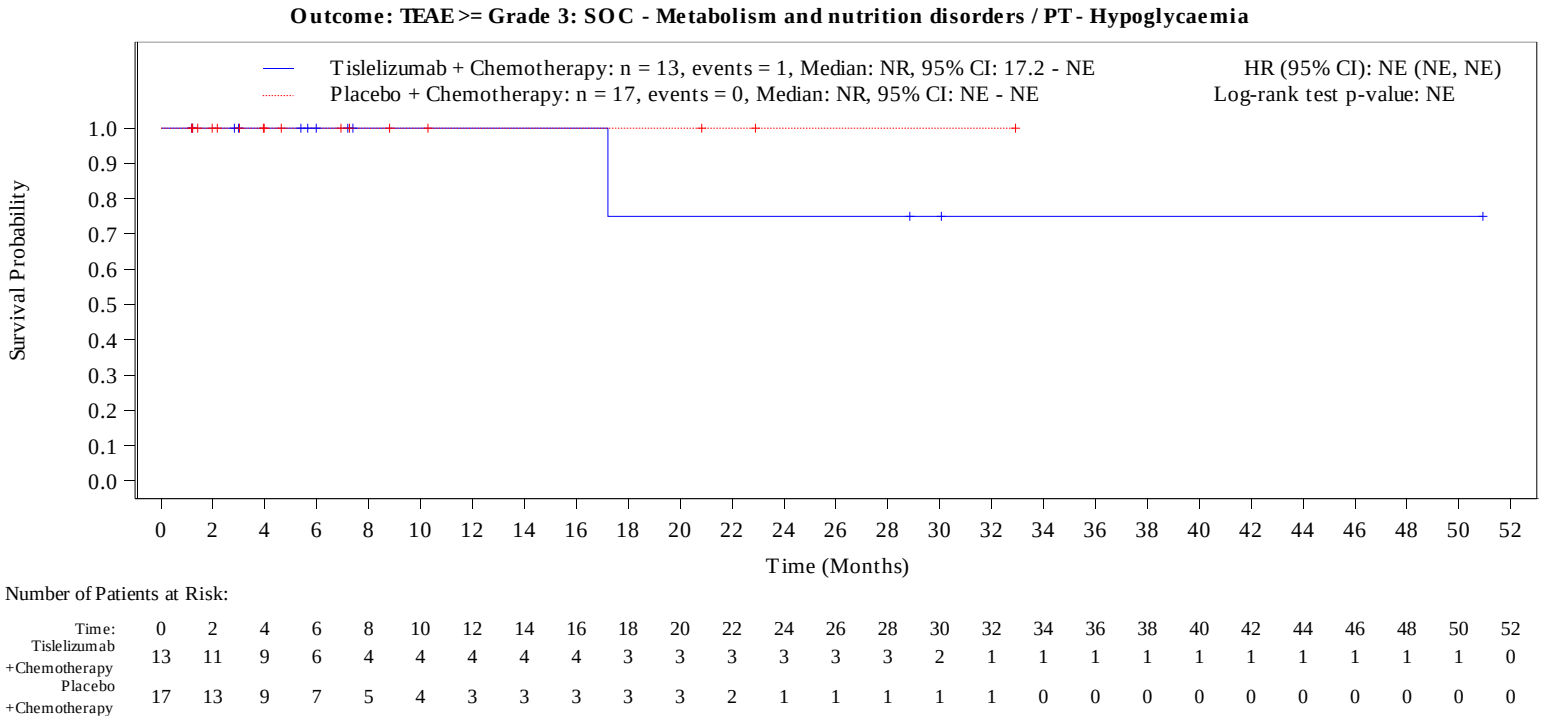

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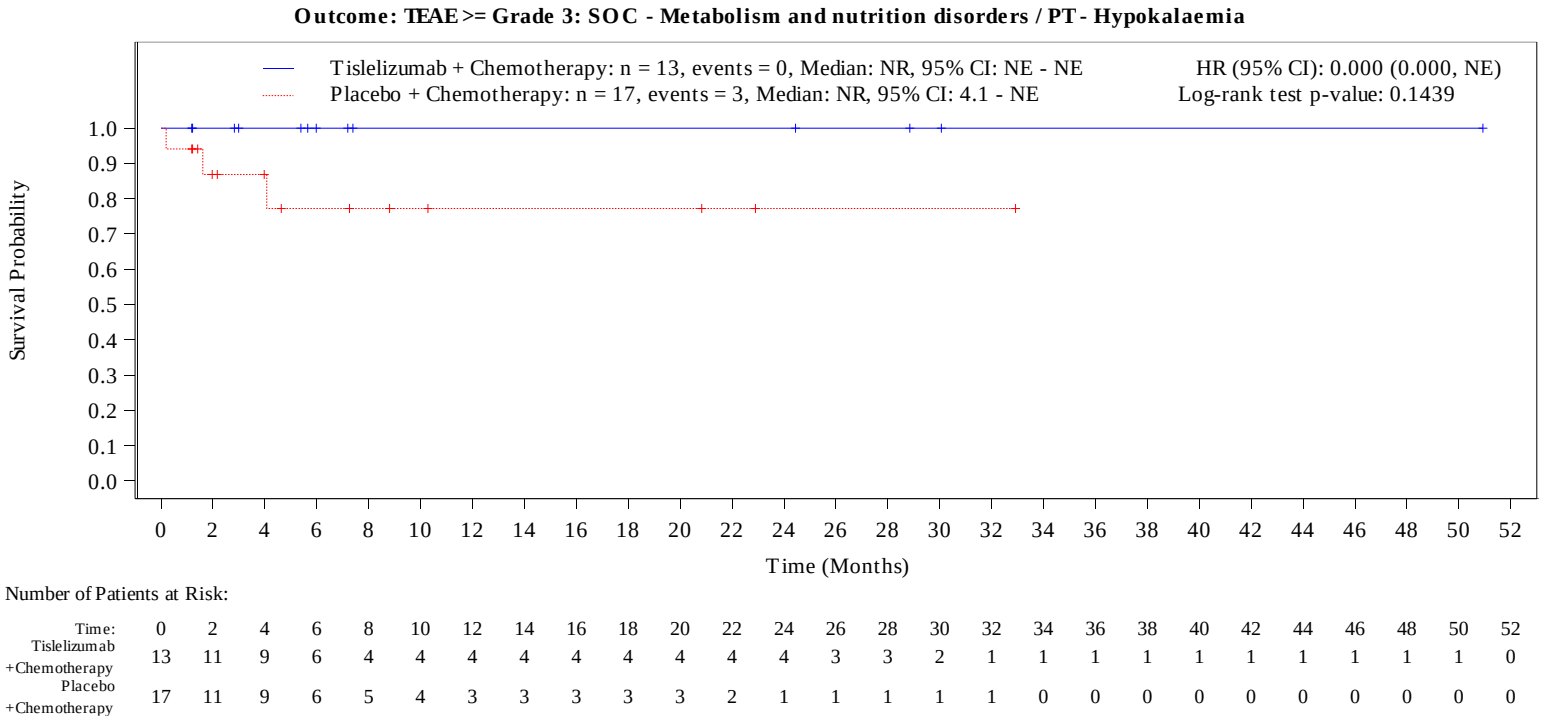

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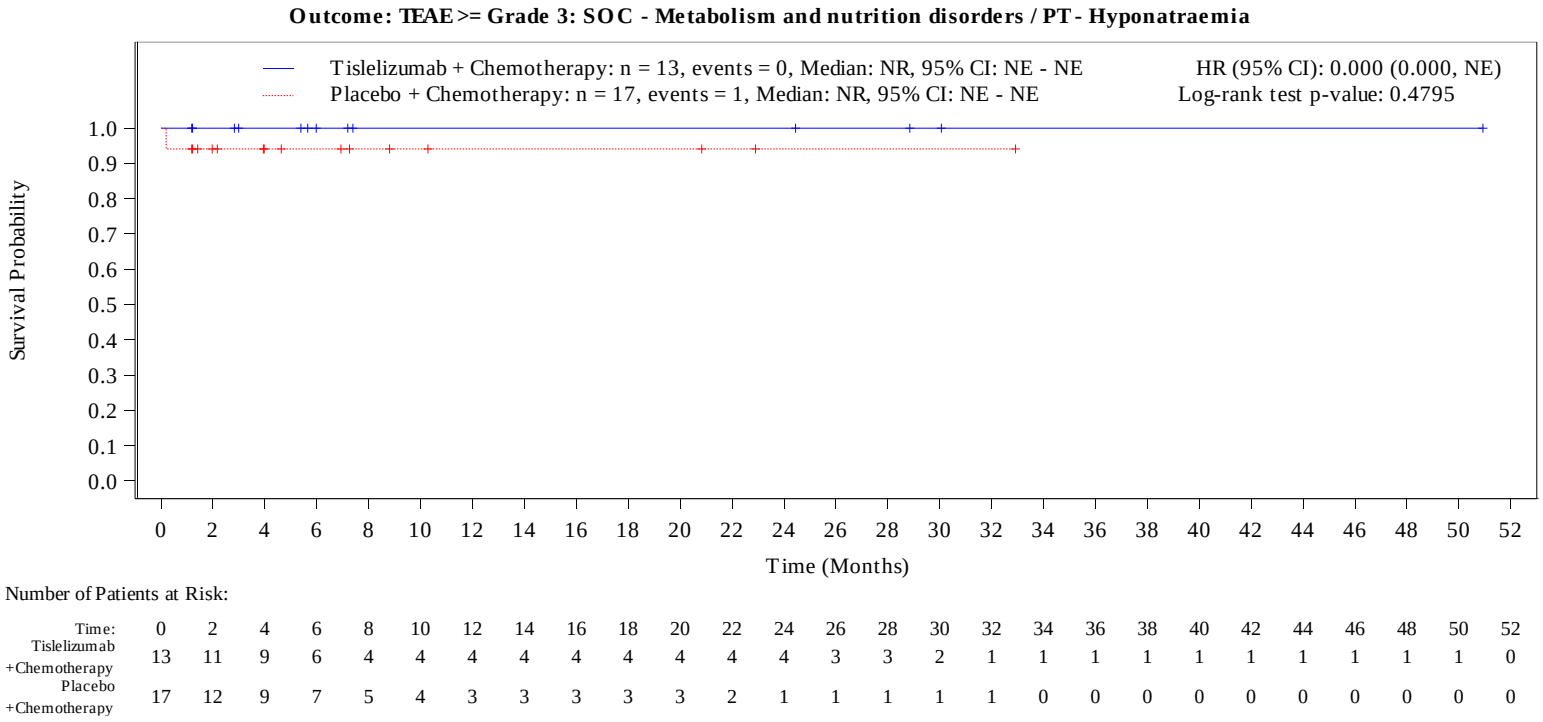

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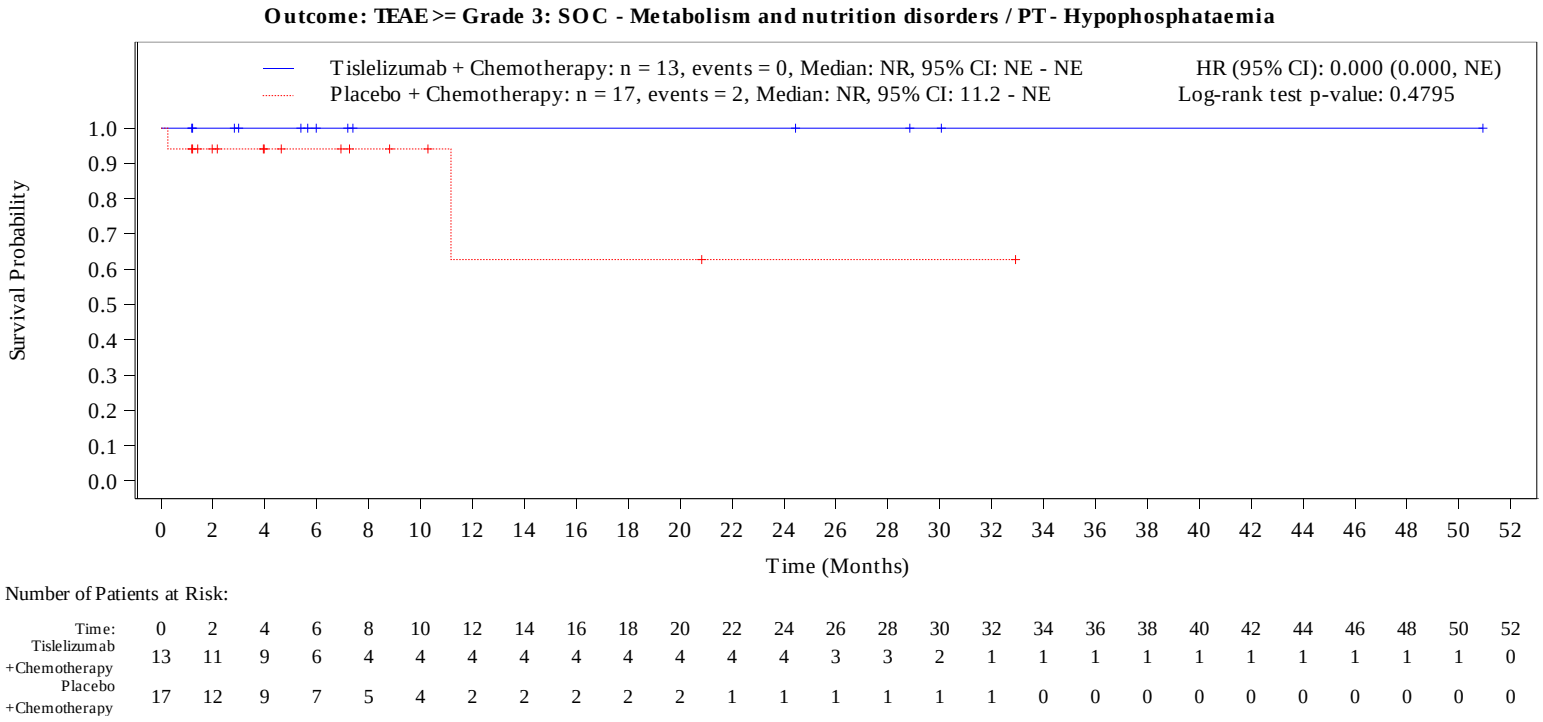

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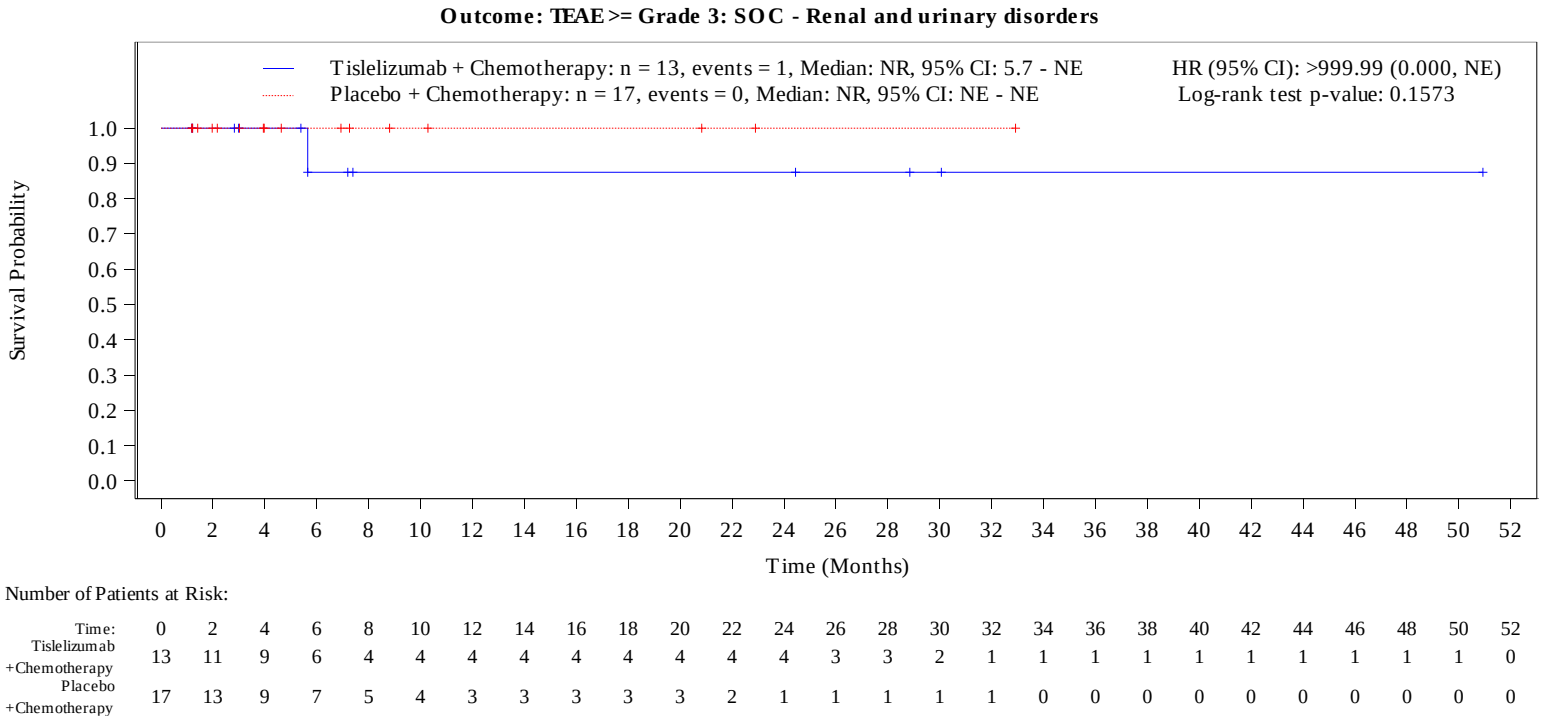

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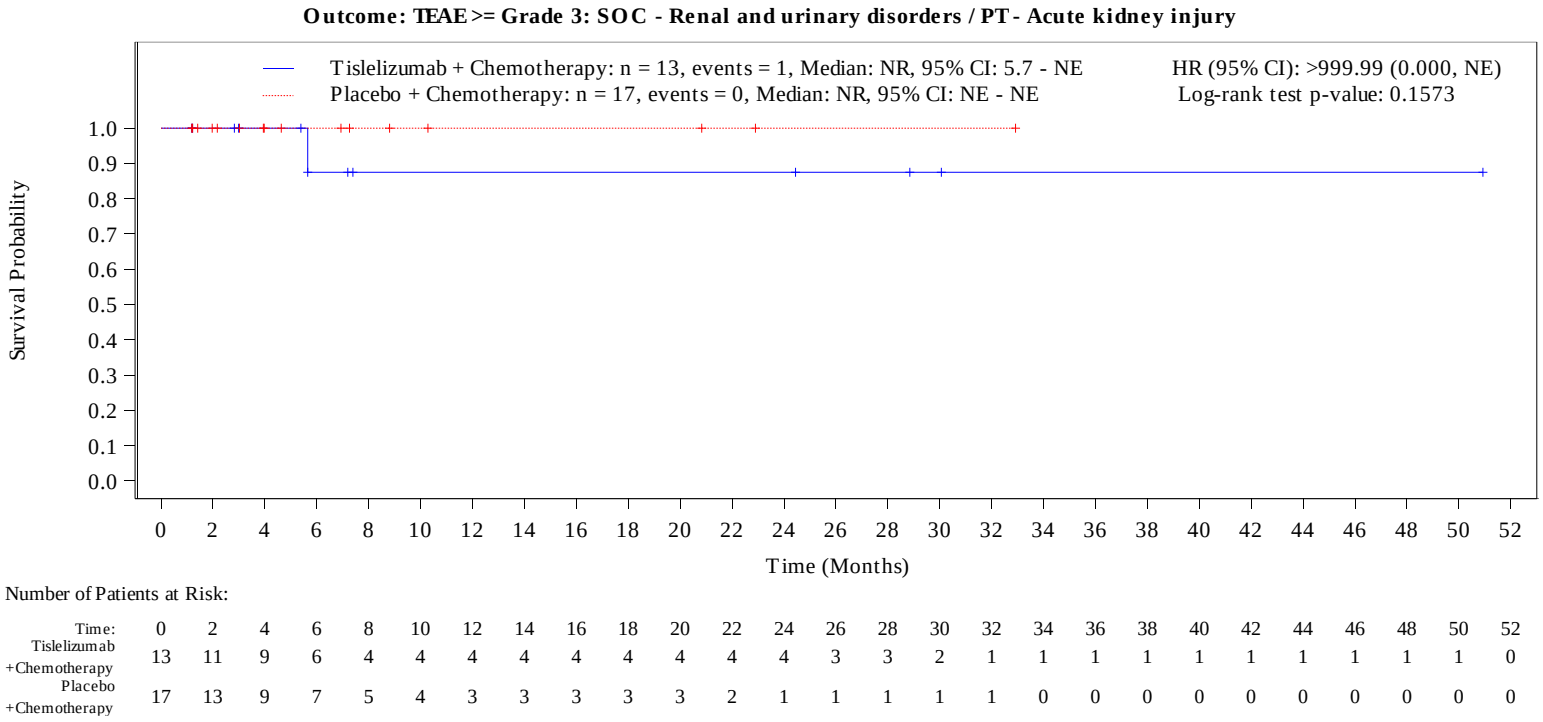

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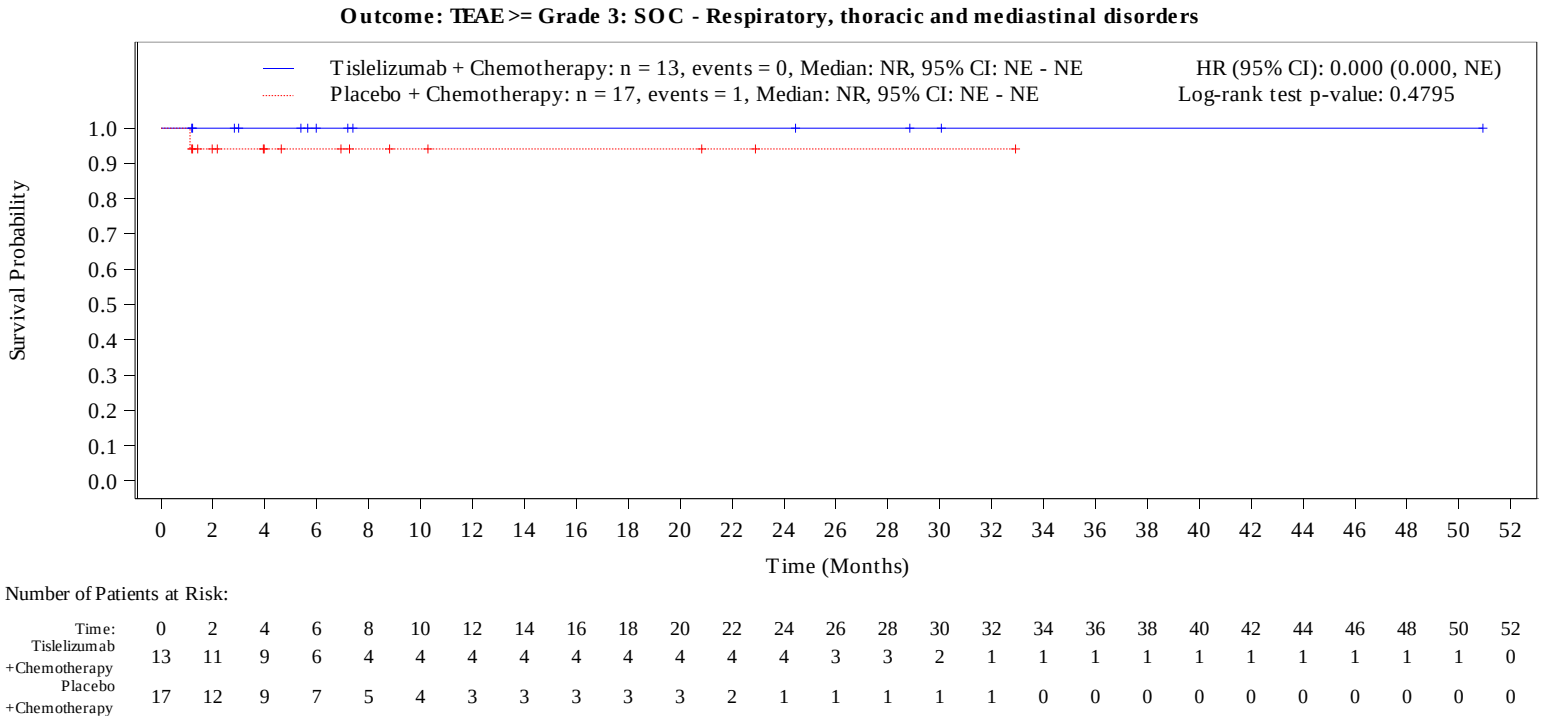

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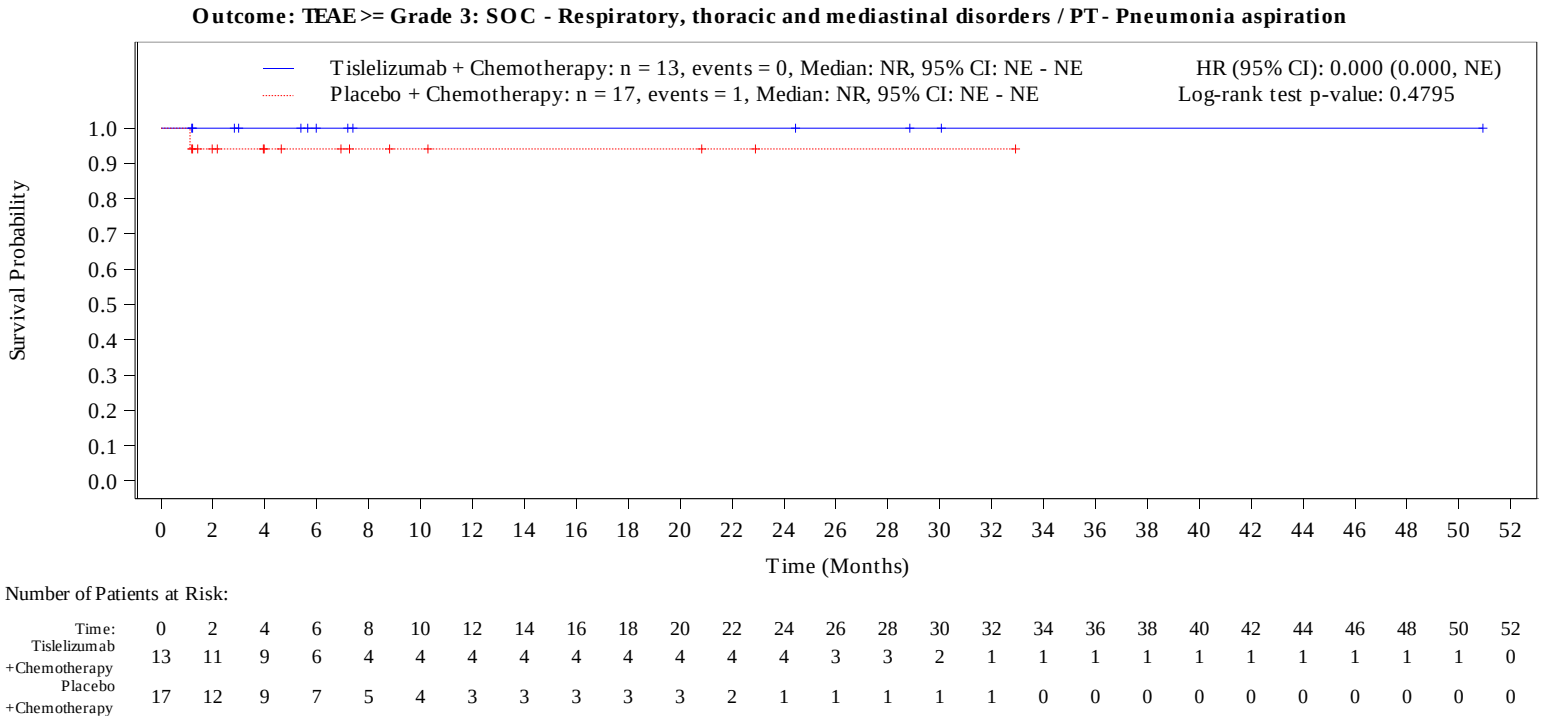

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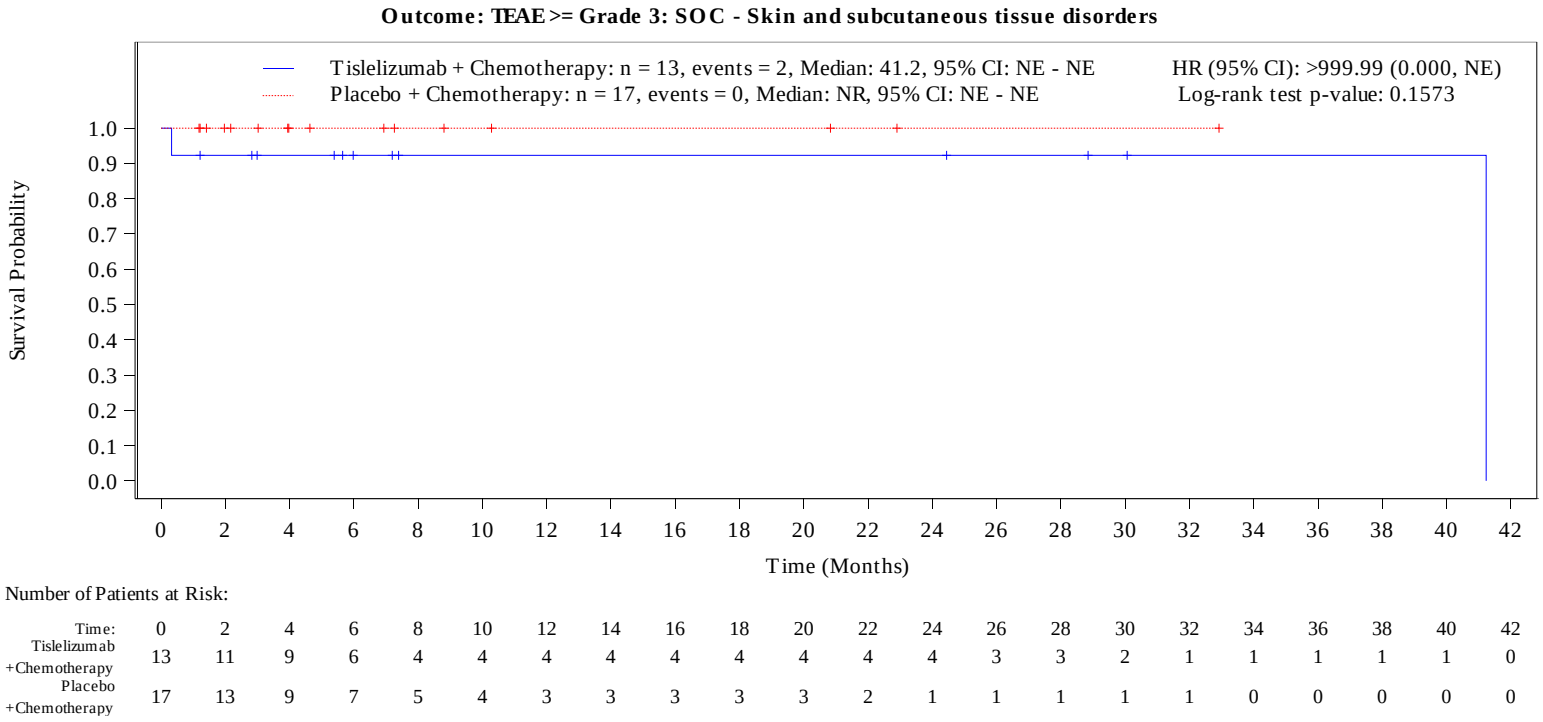

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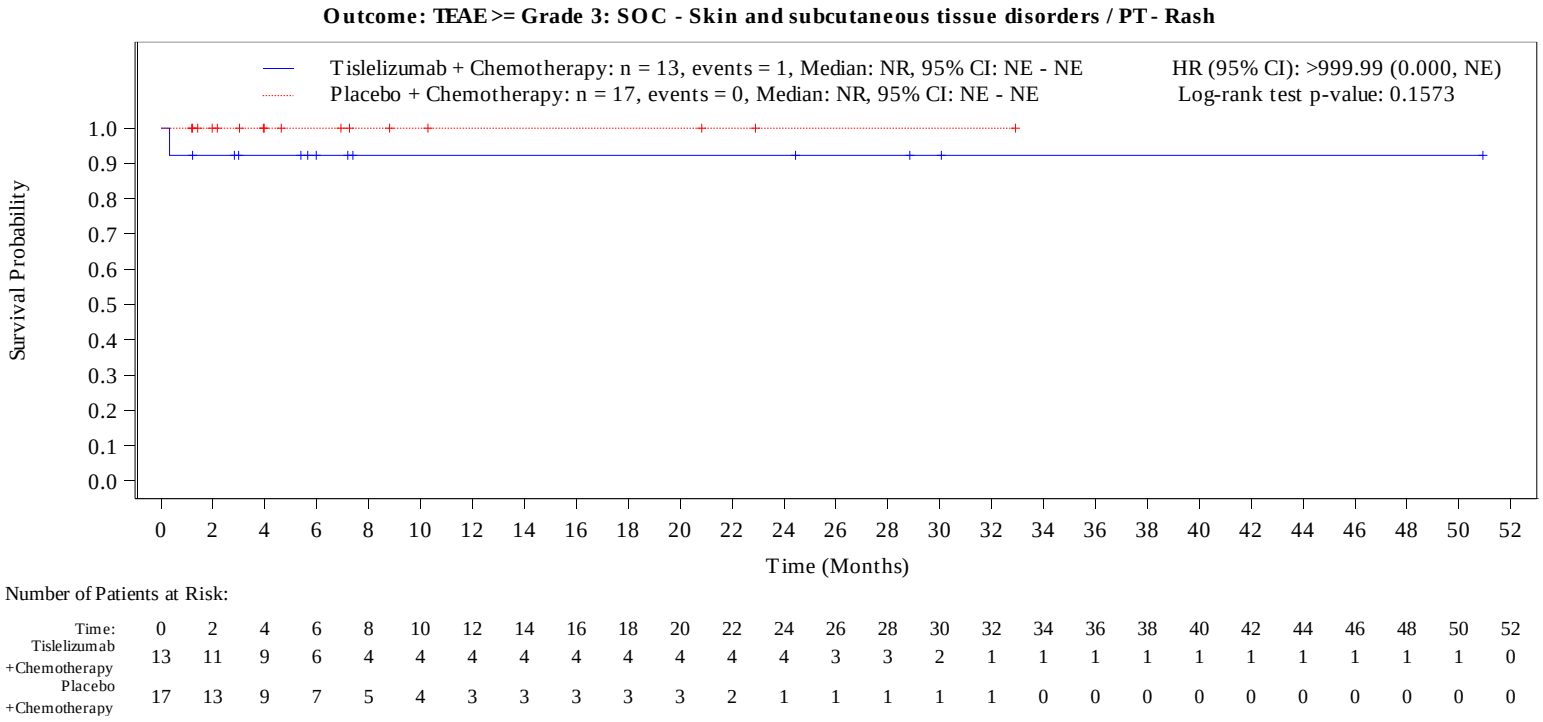

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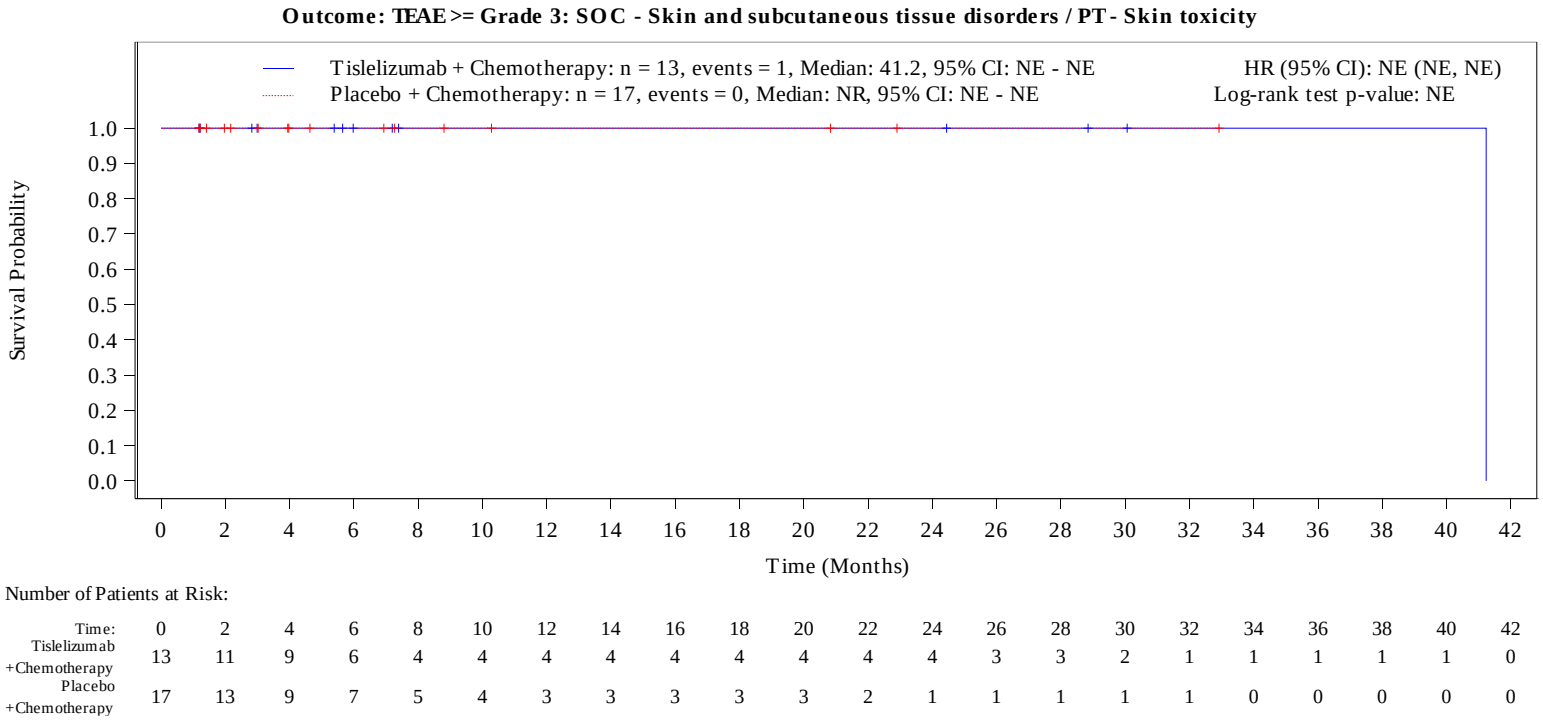

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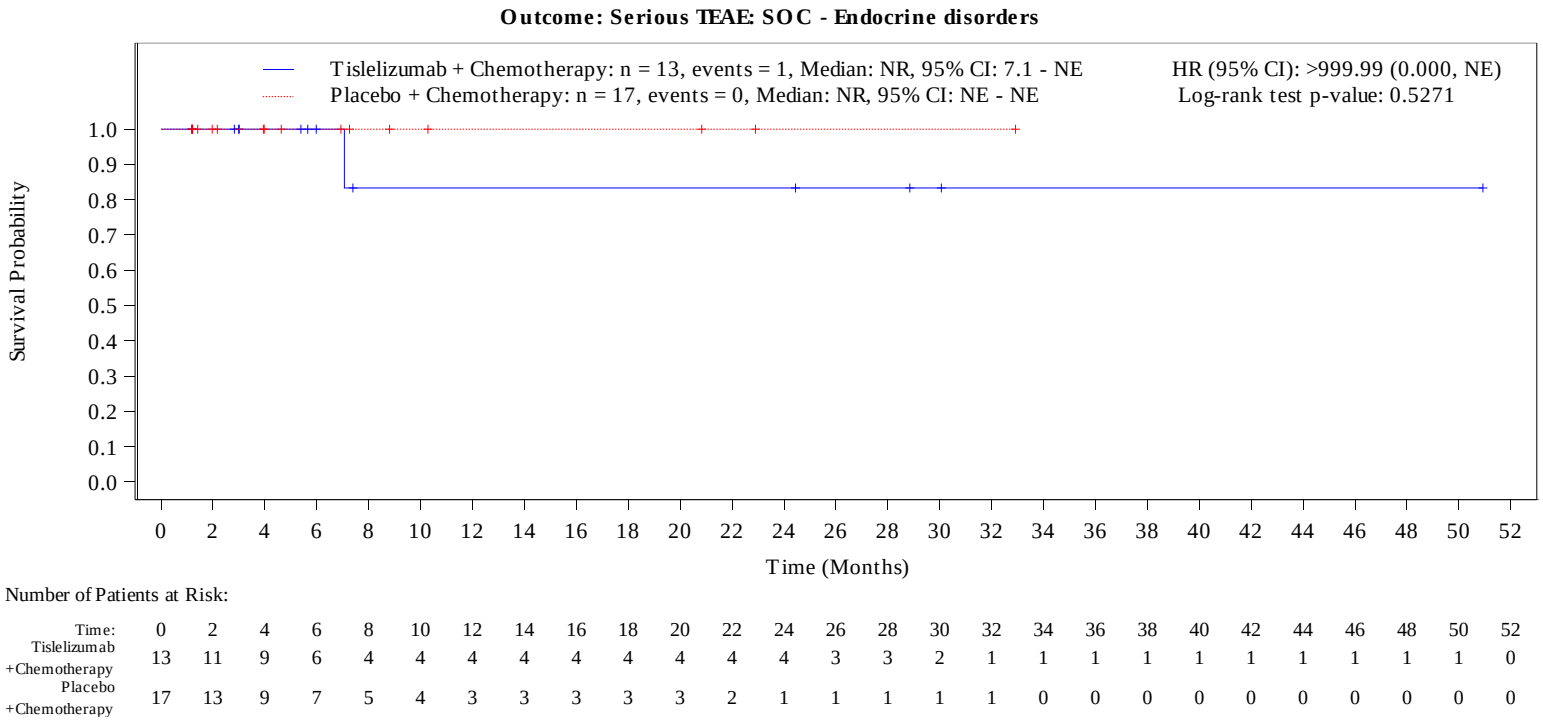
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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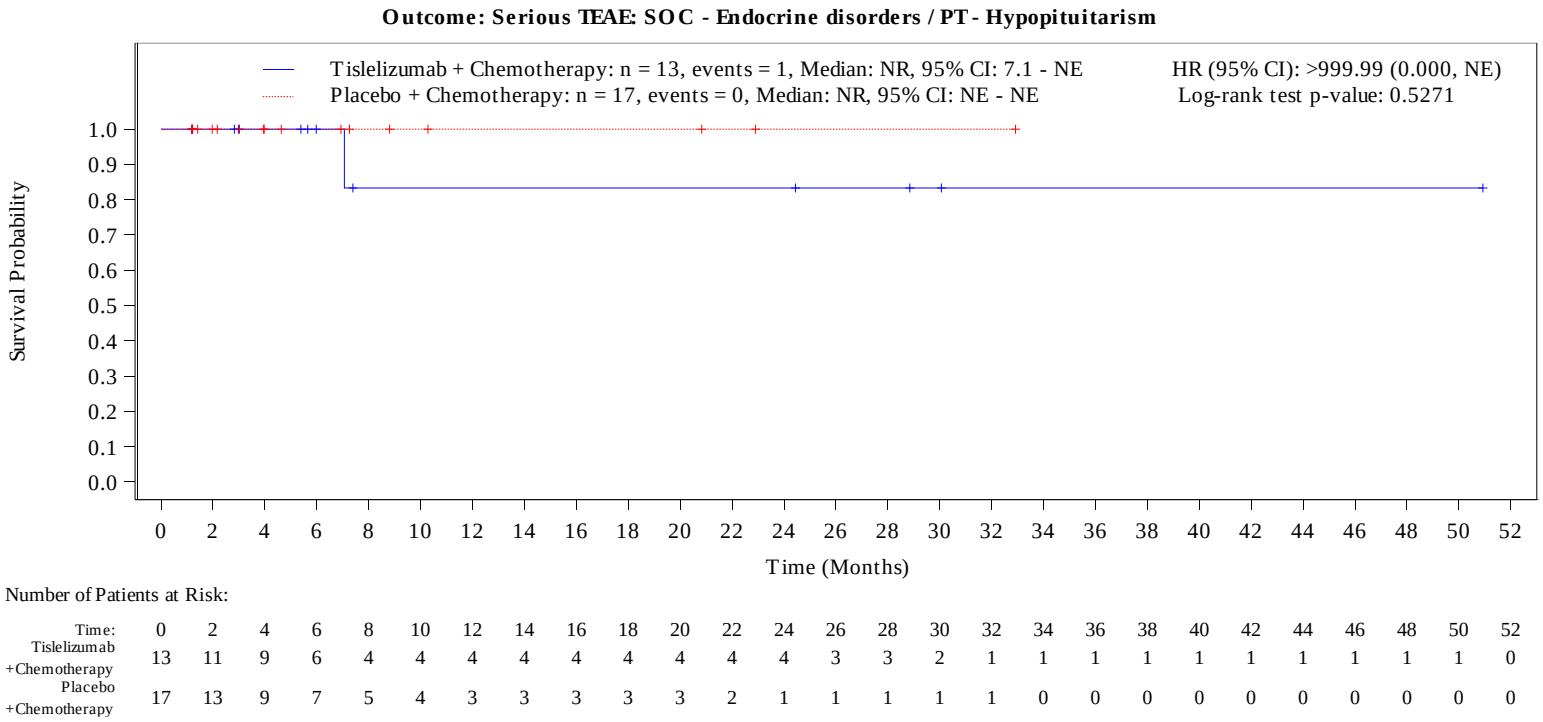

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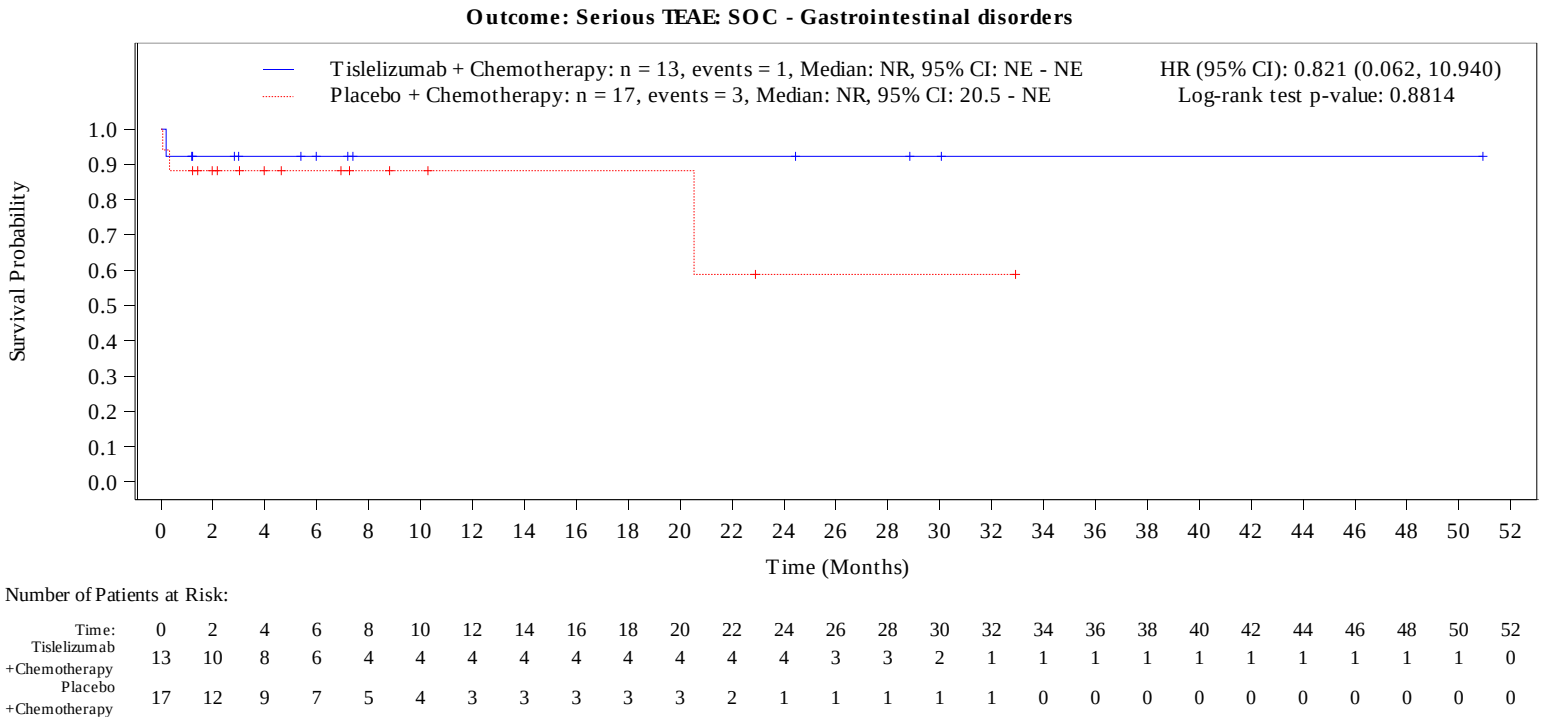

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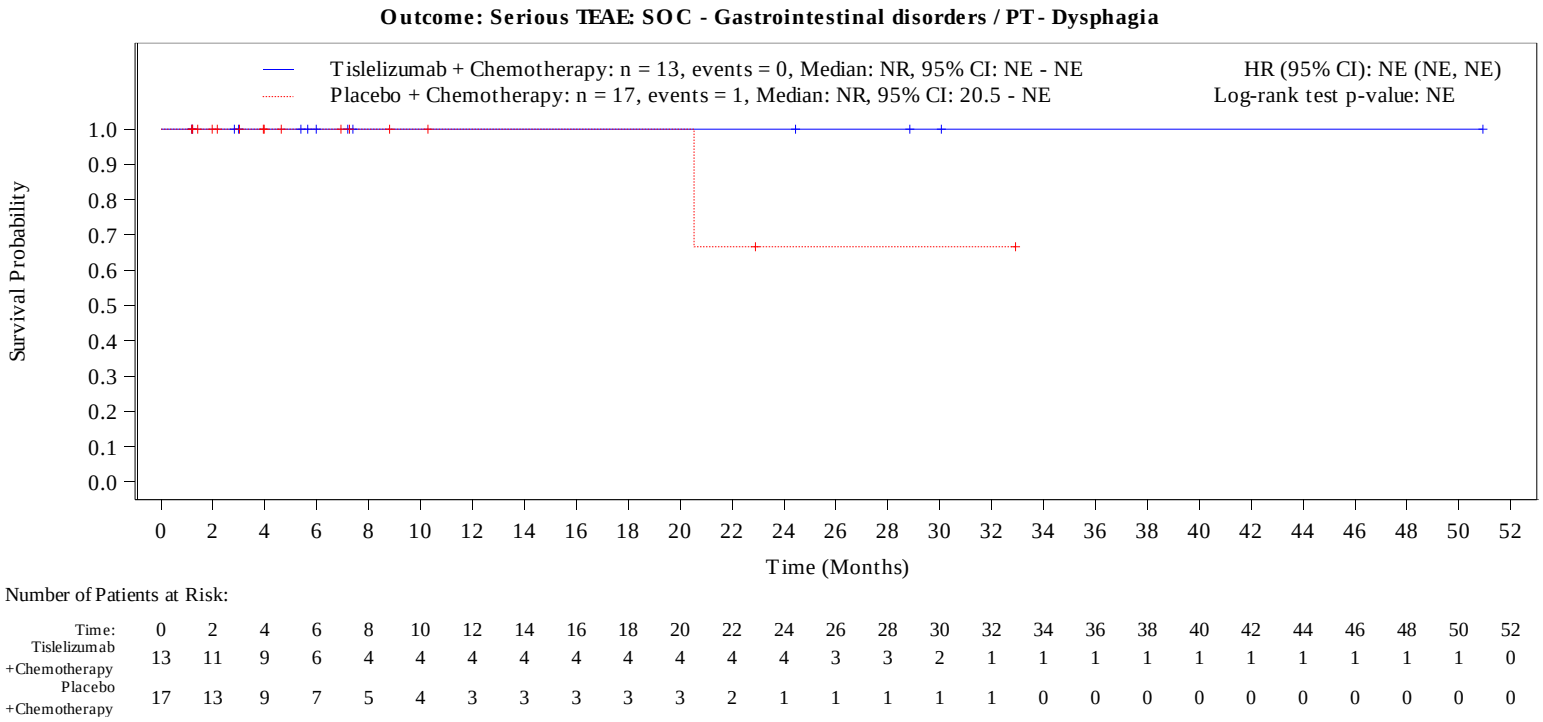

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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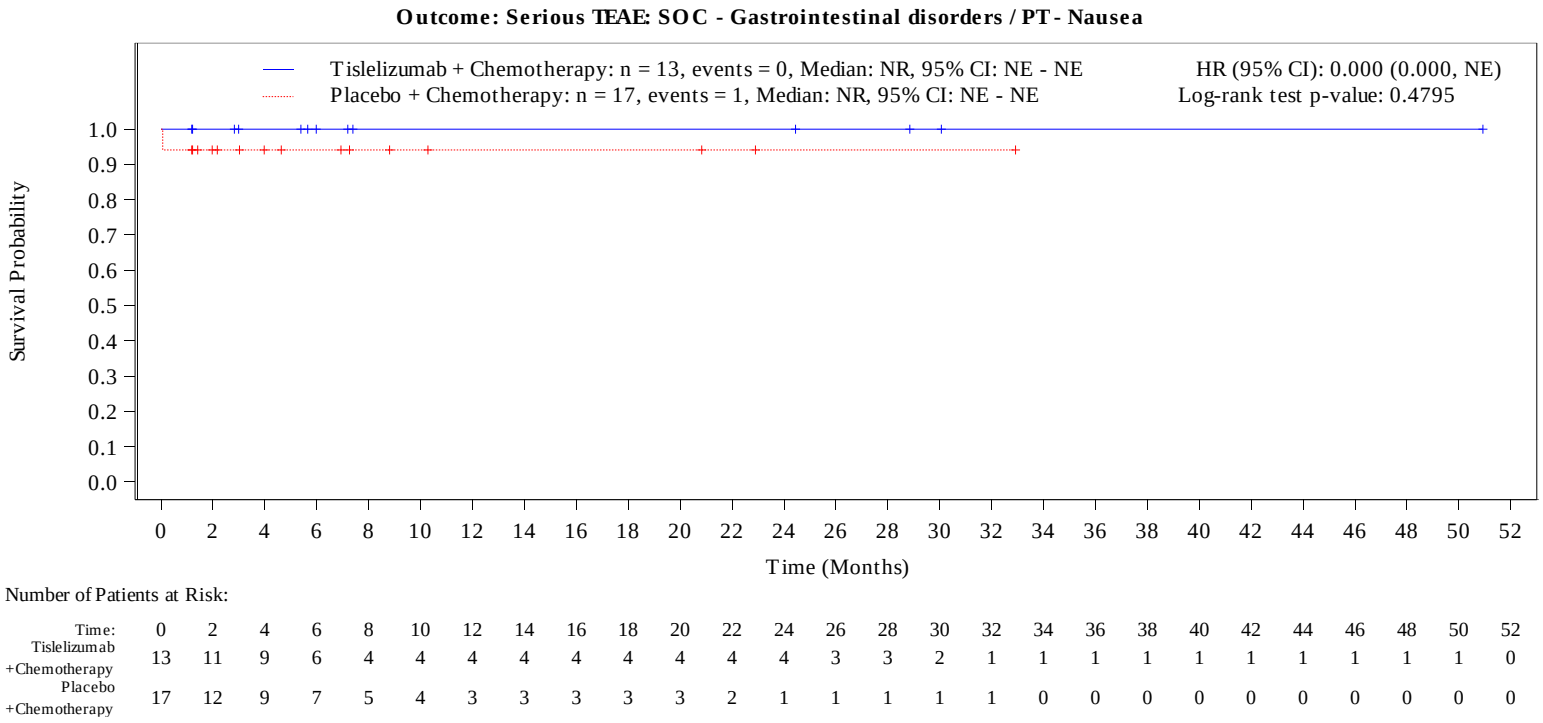

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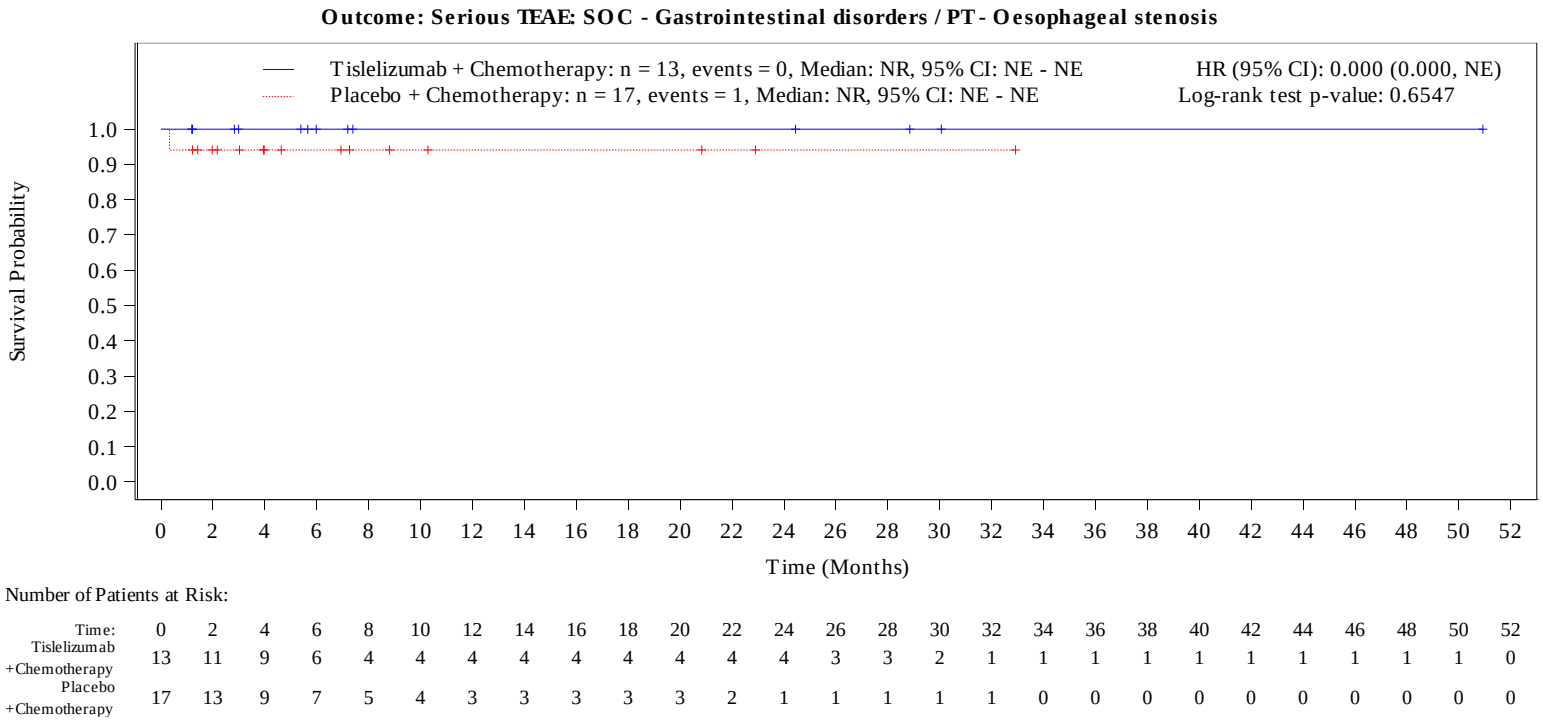

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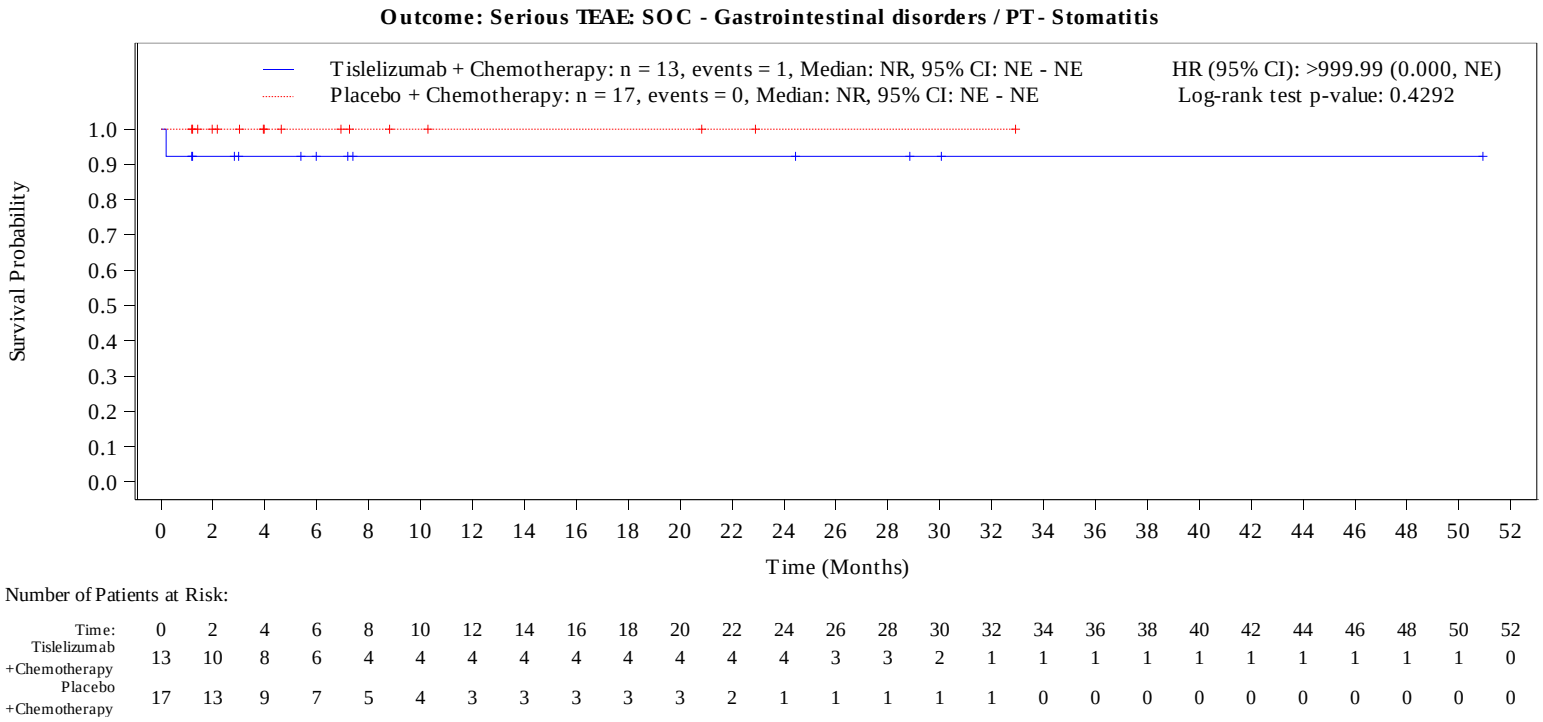

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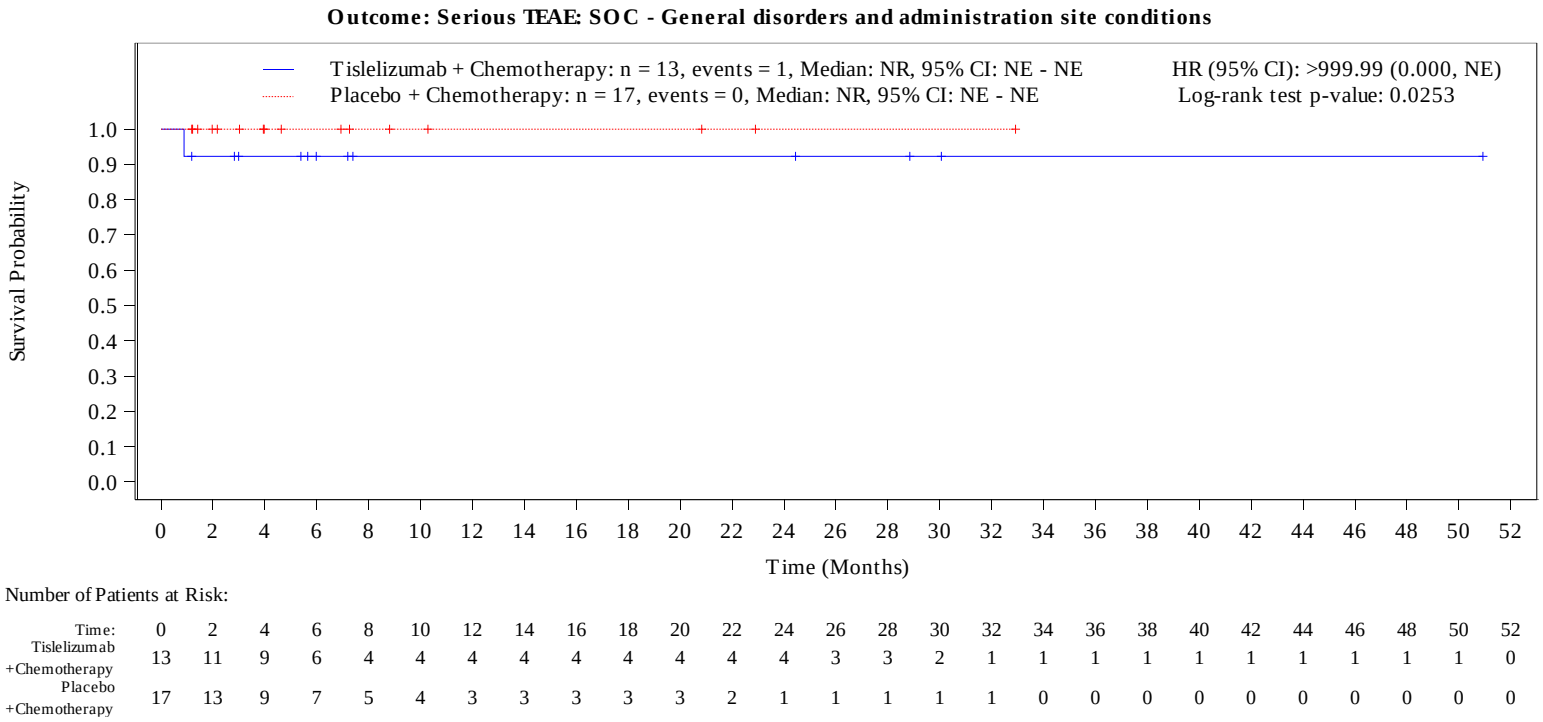

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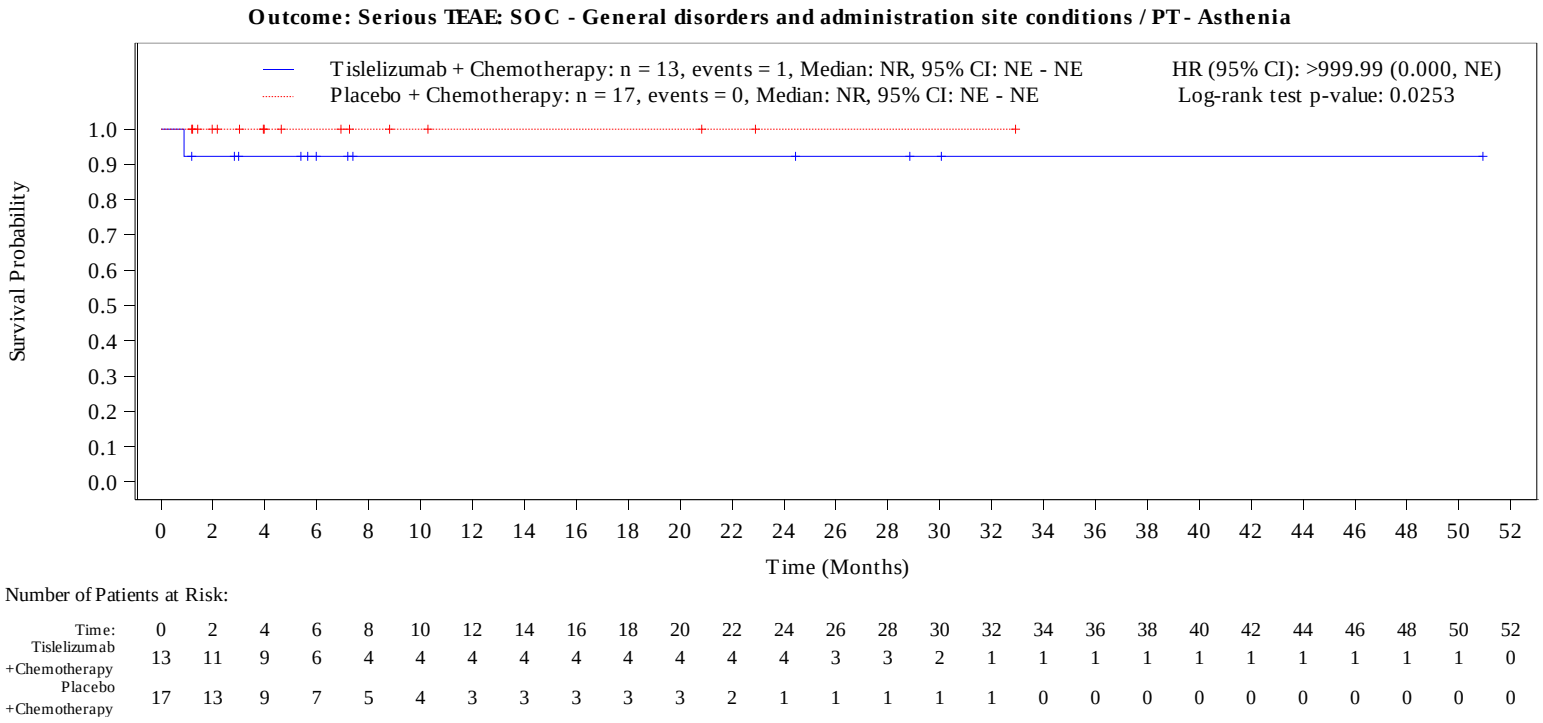

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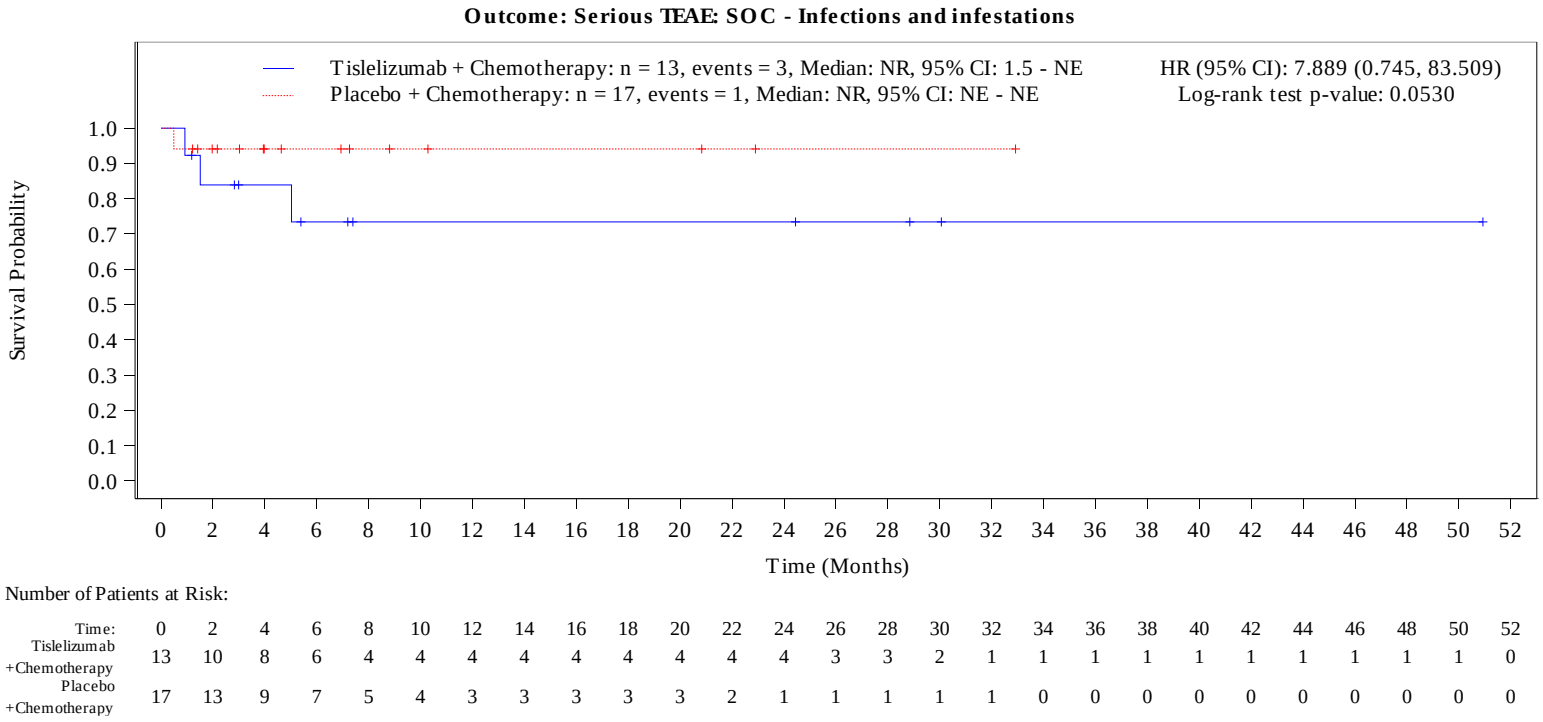

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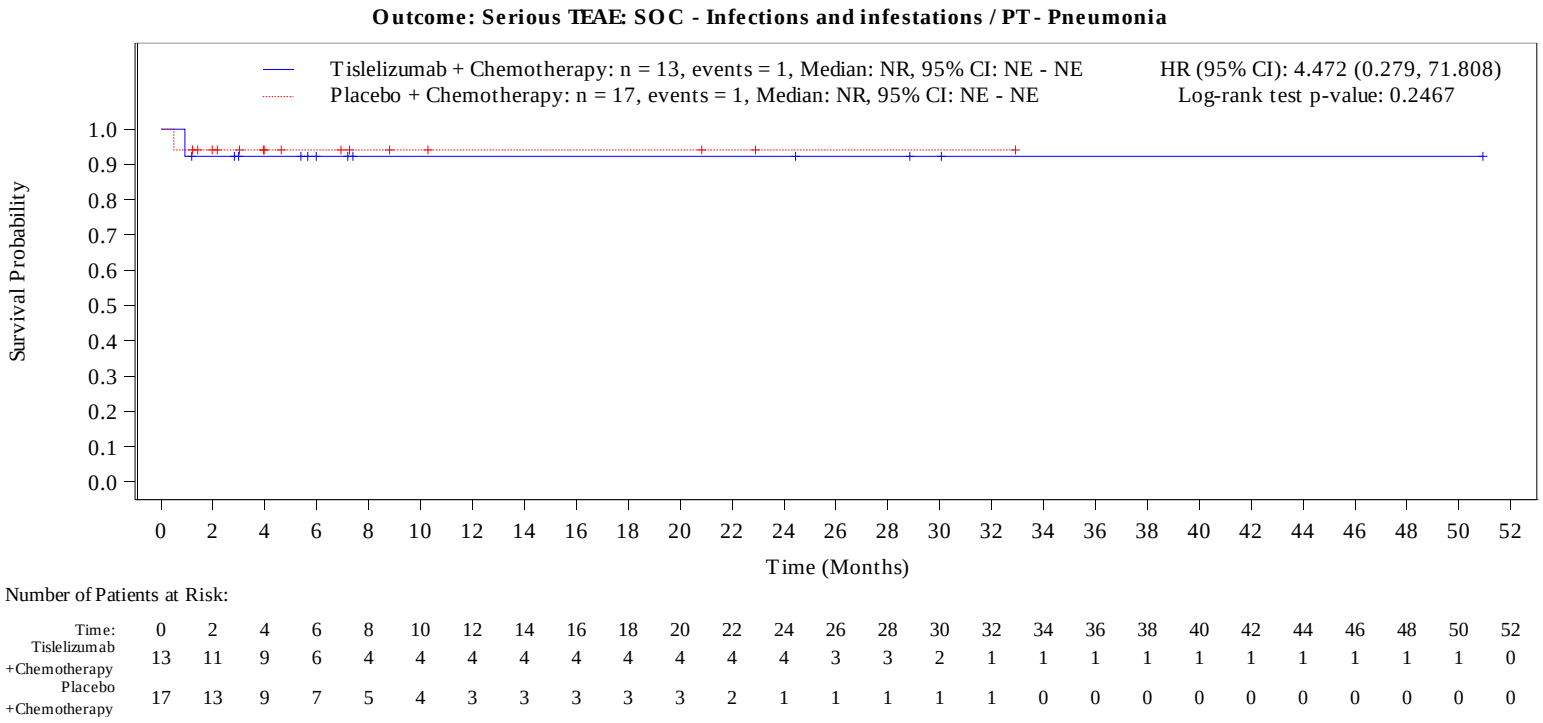

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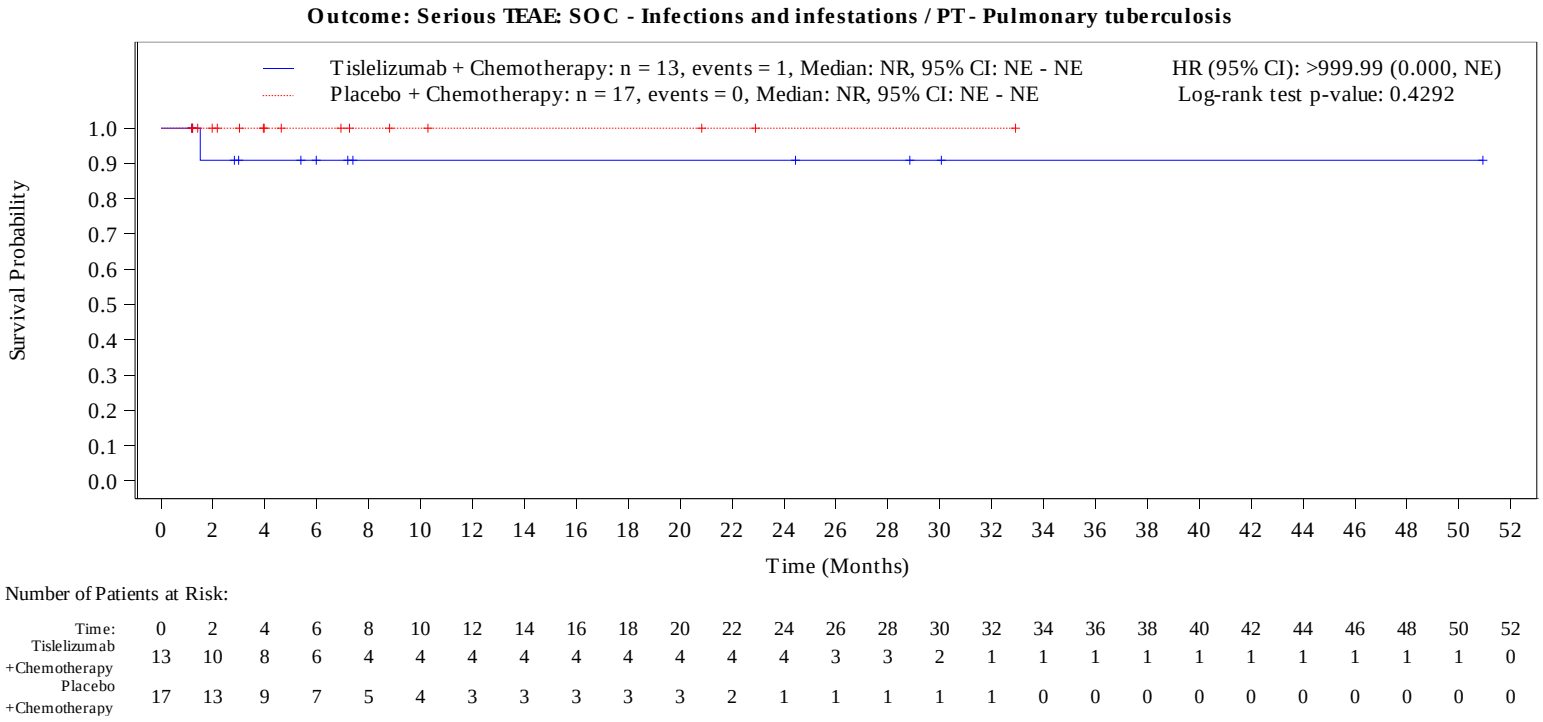

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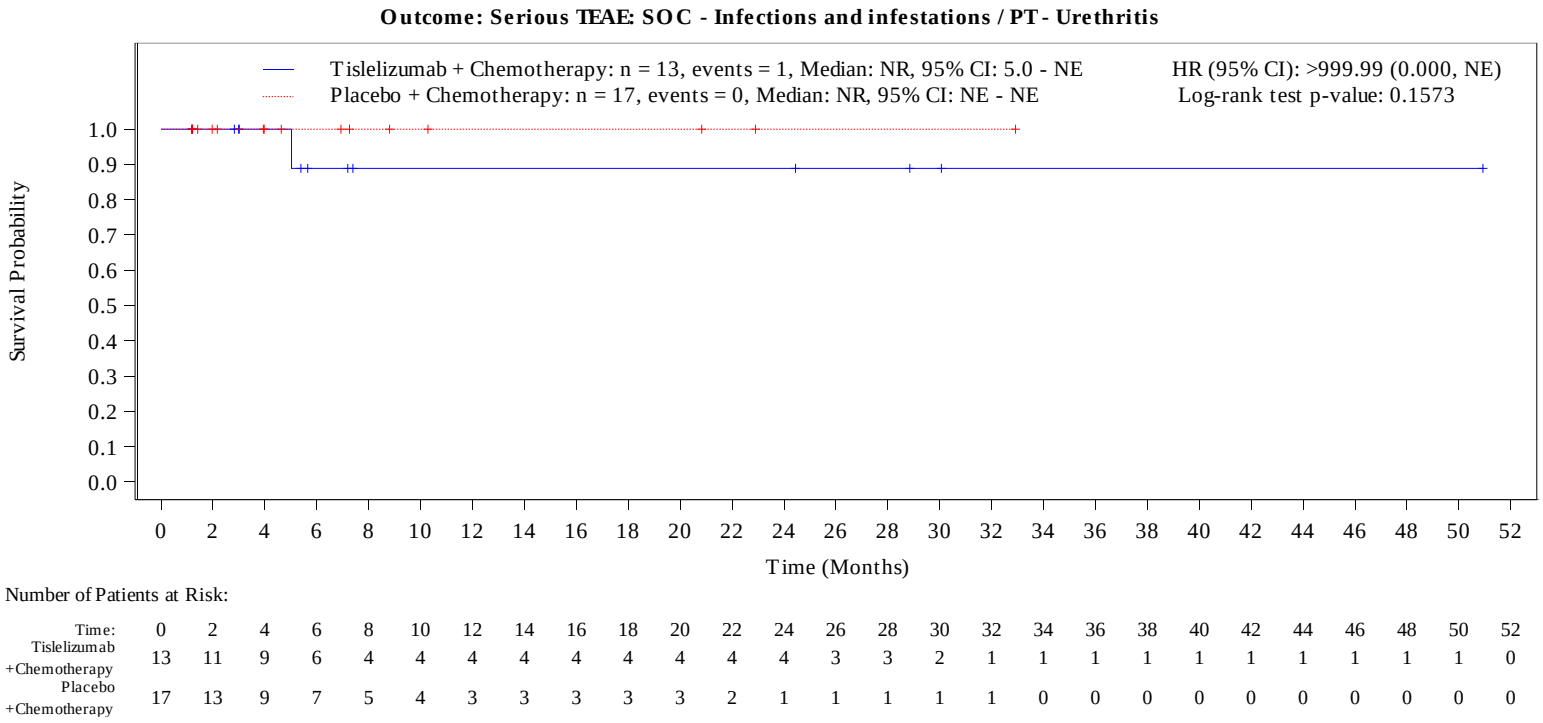

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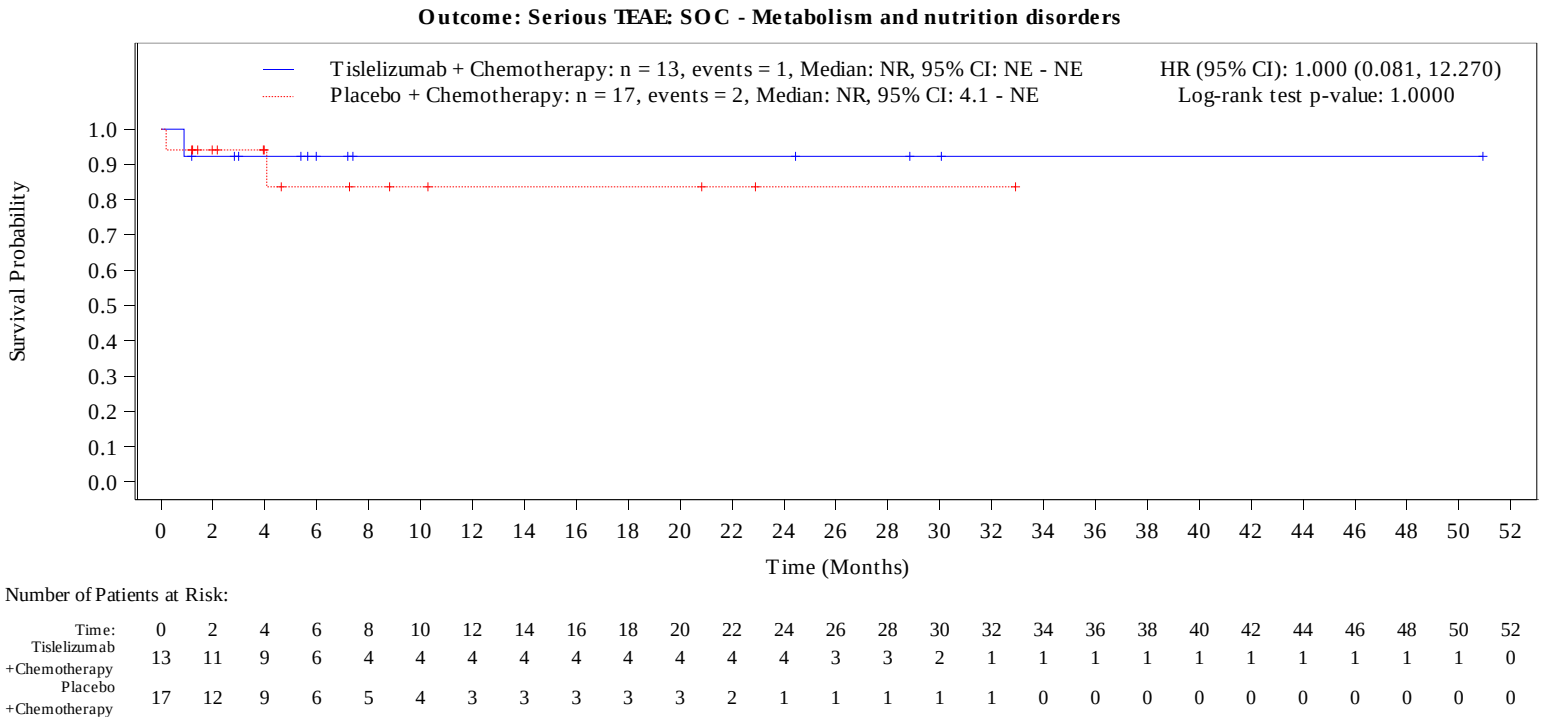

Number of Patients at Risk:

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Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	9	6	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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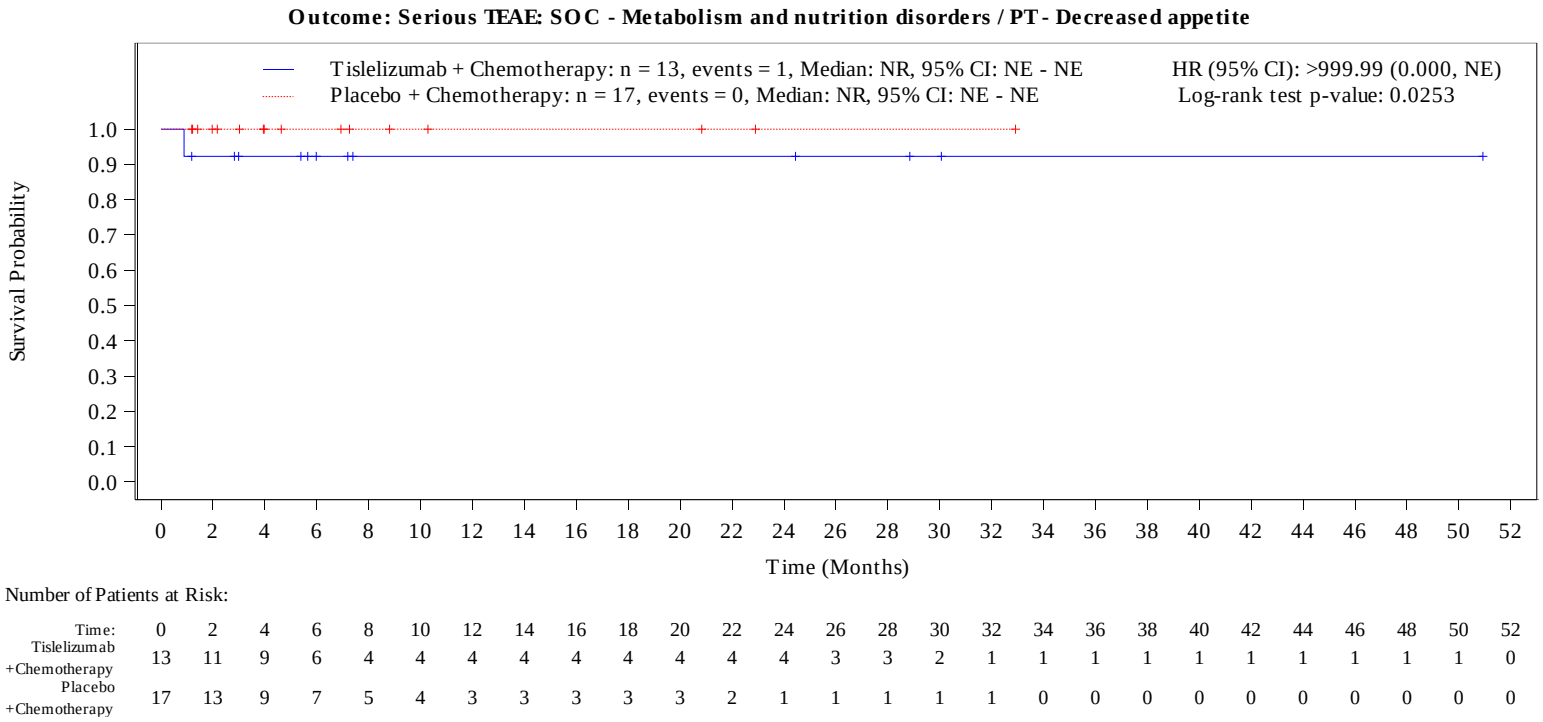

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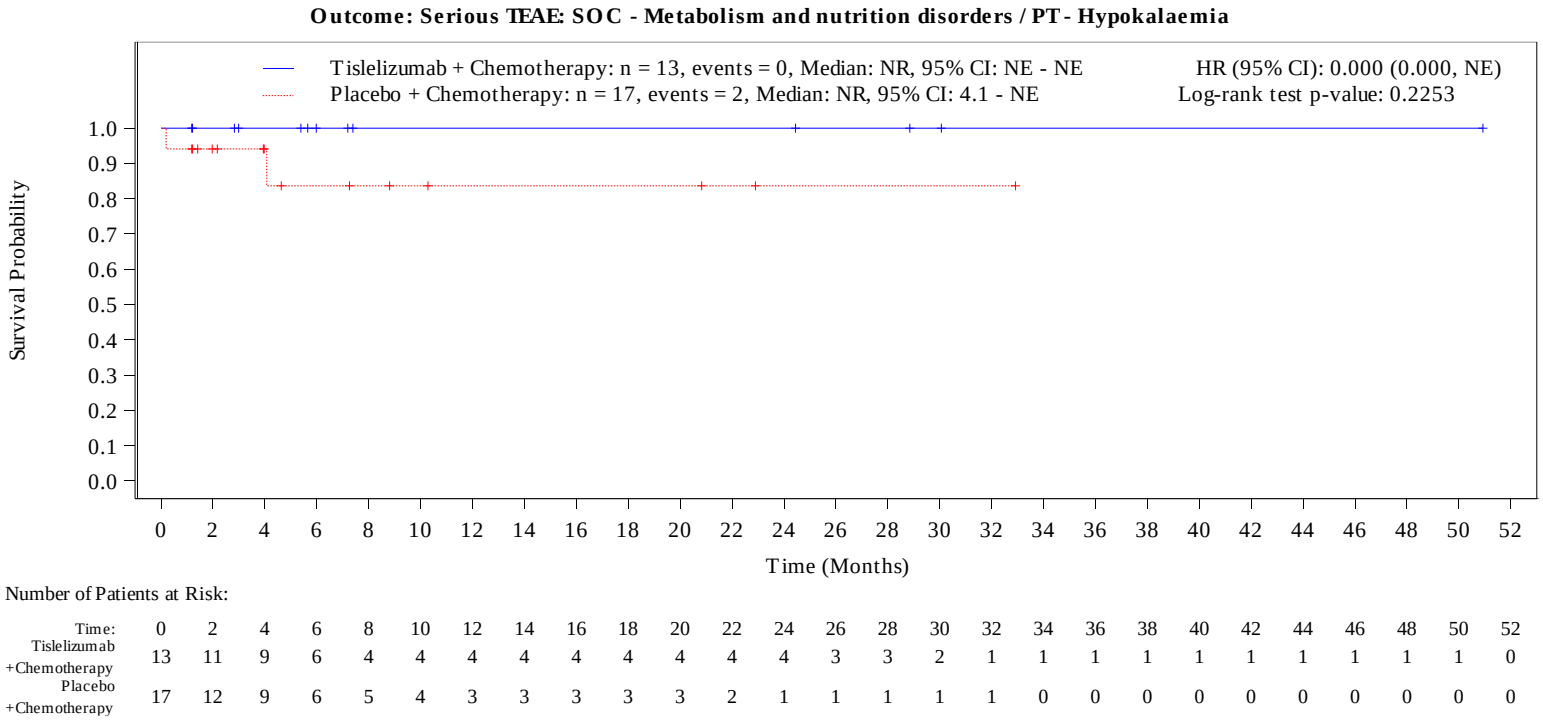

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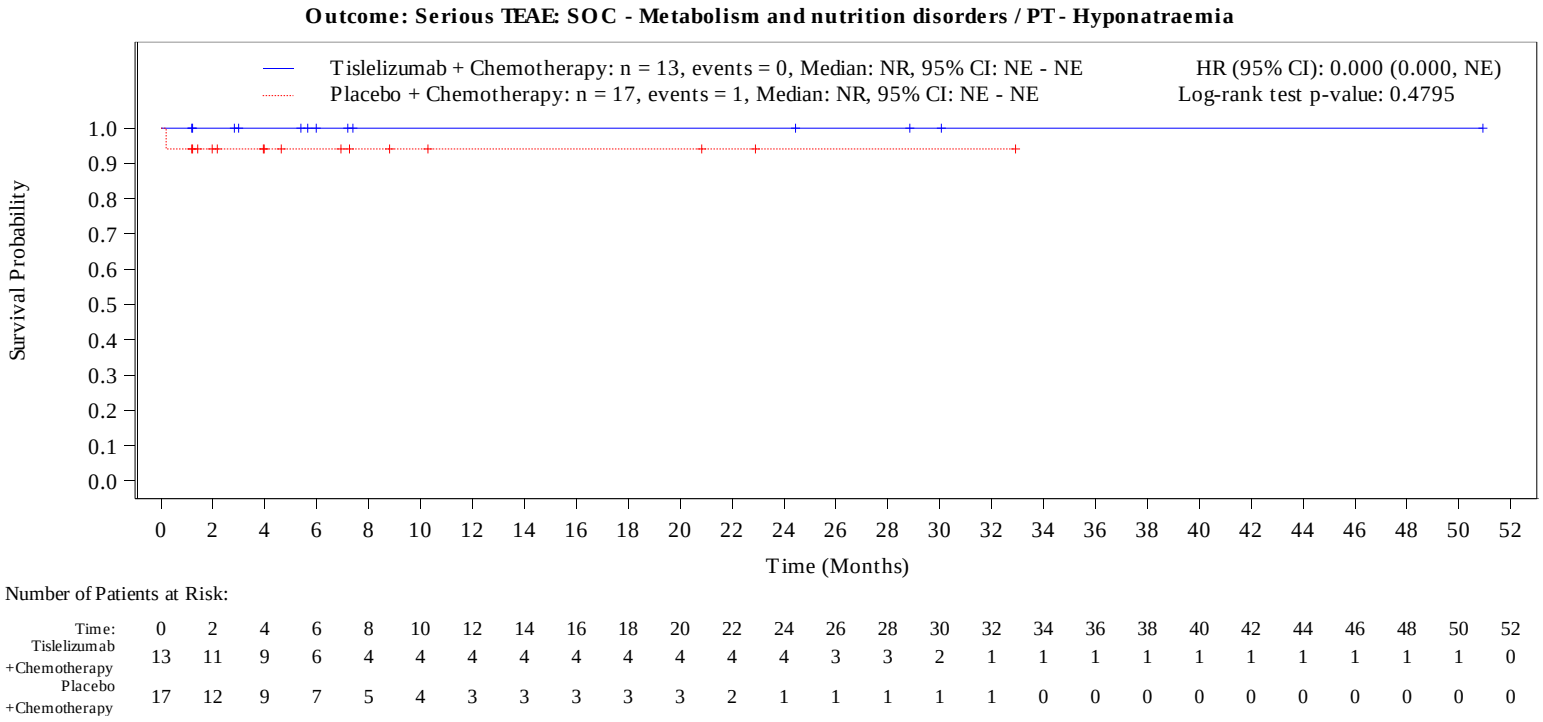

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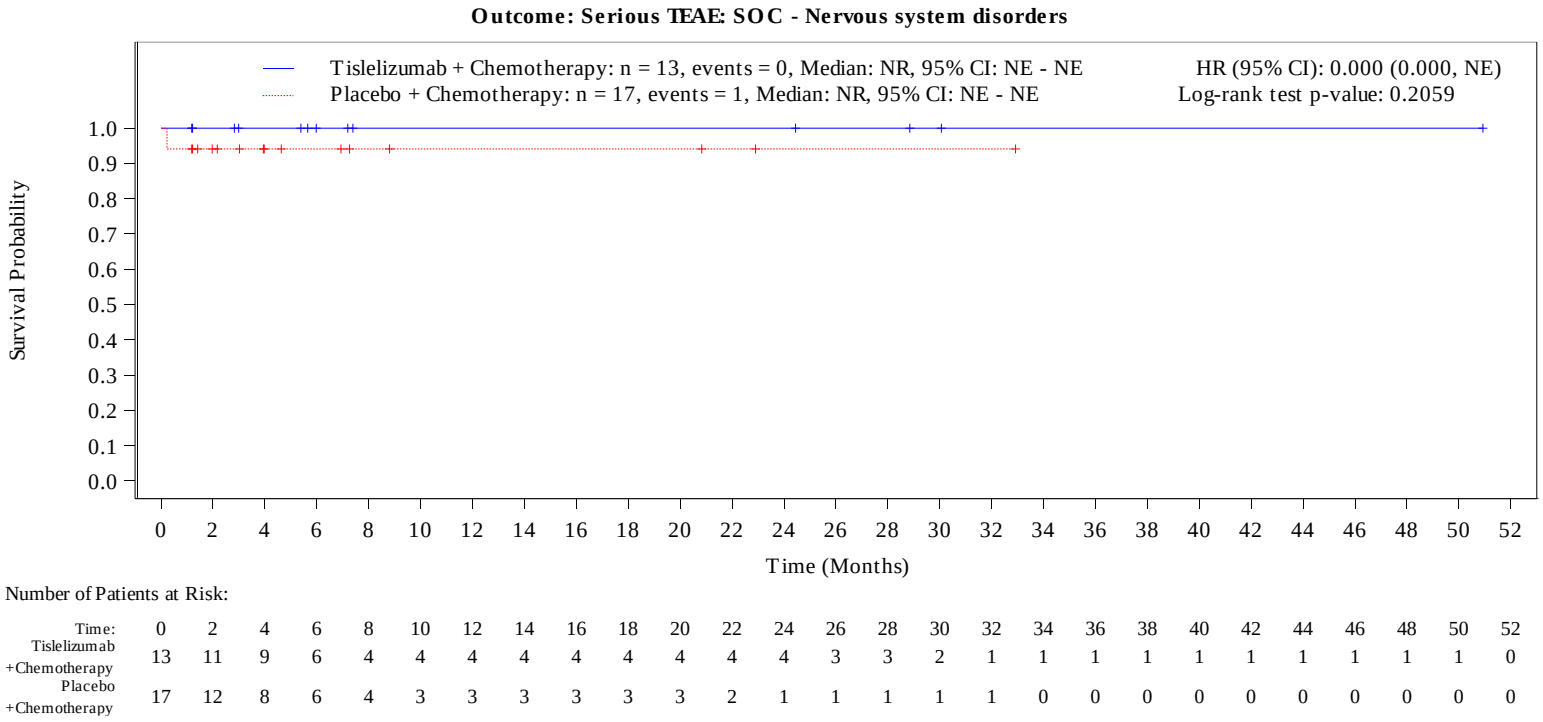

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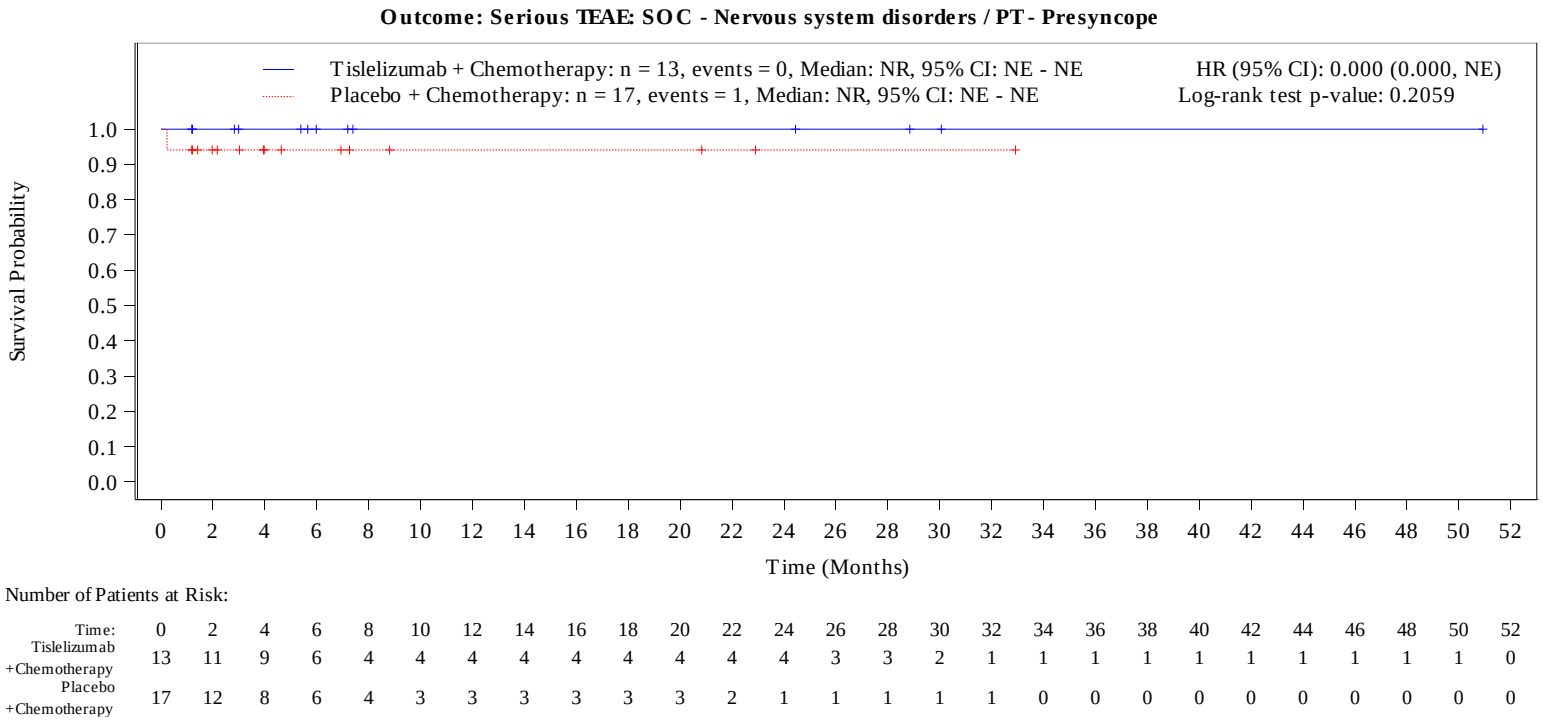

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
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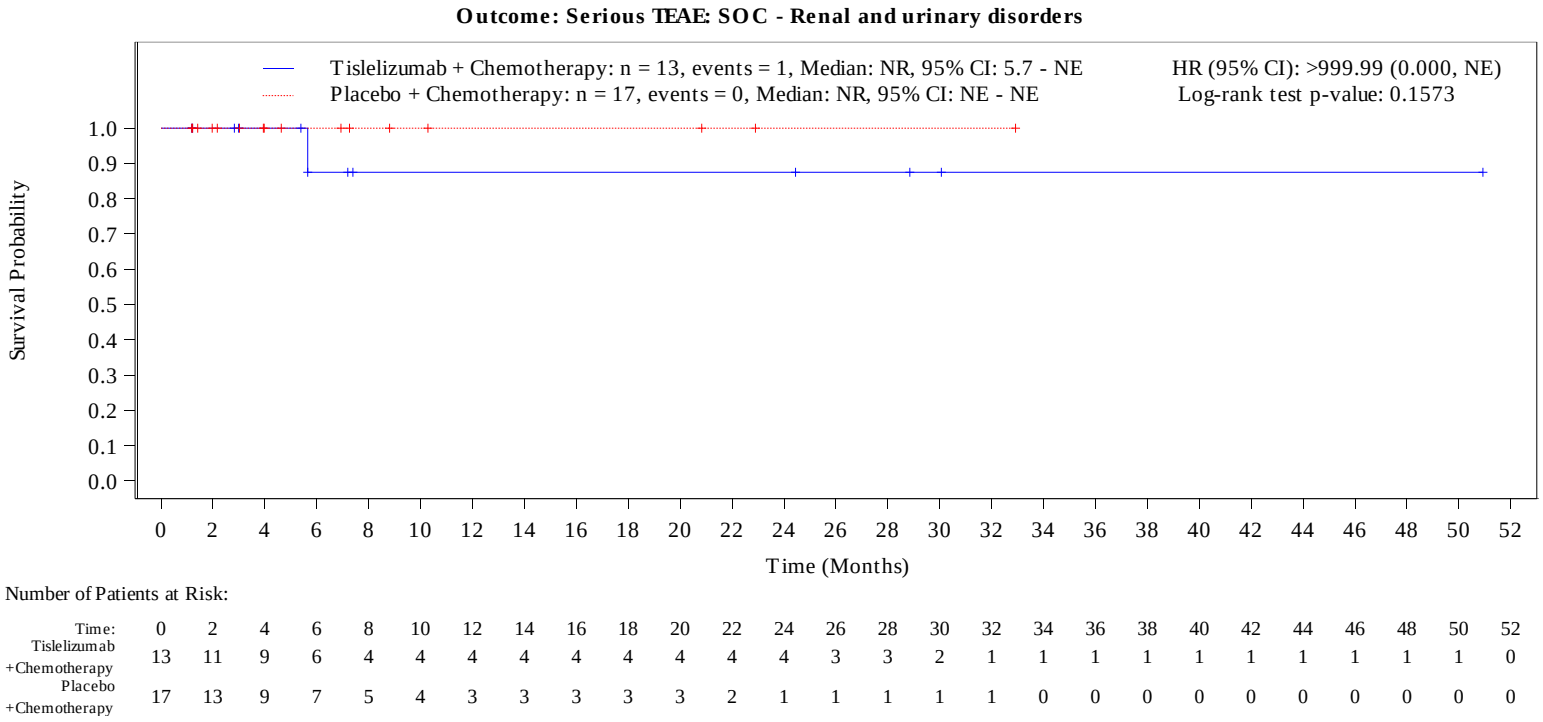
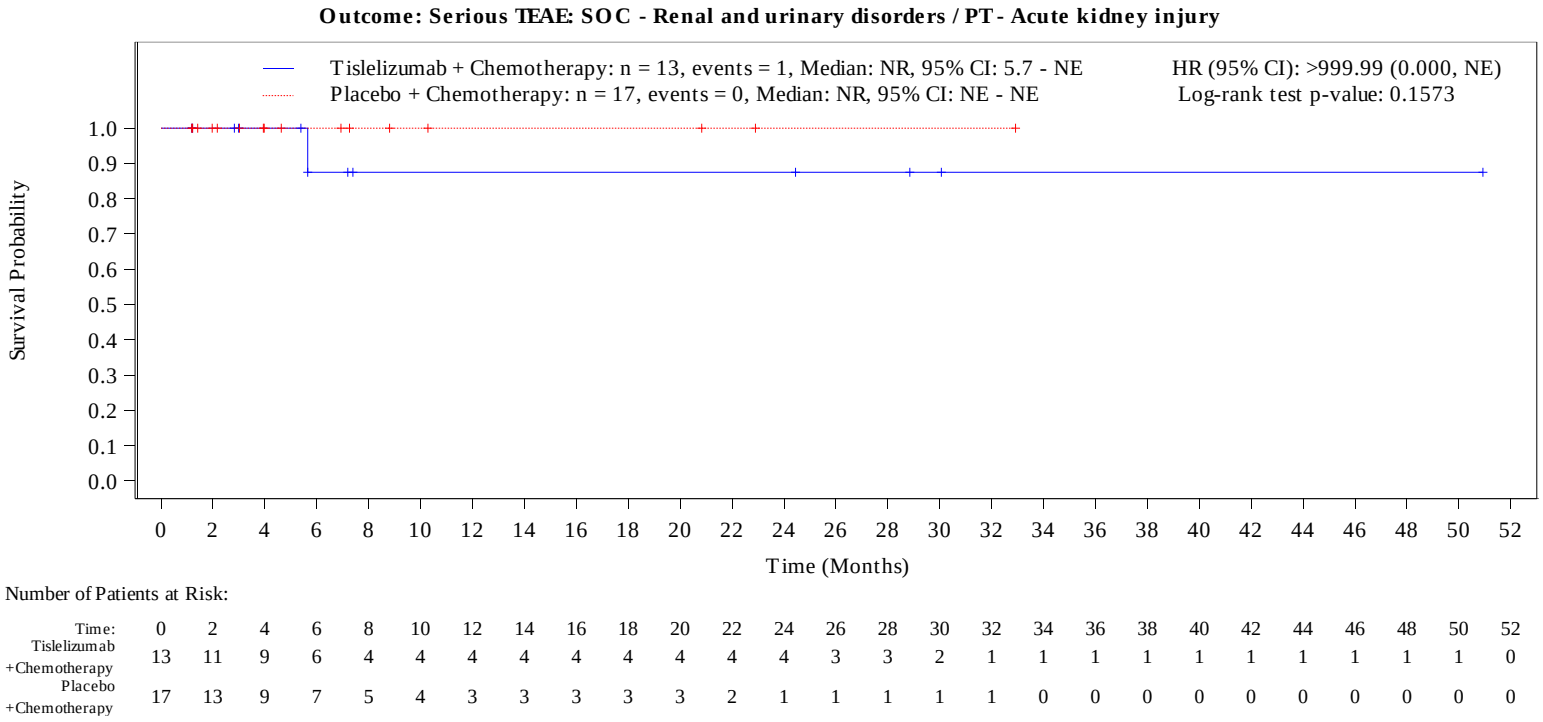
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-4-km-aesocpt-ser-pop1-3y.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



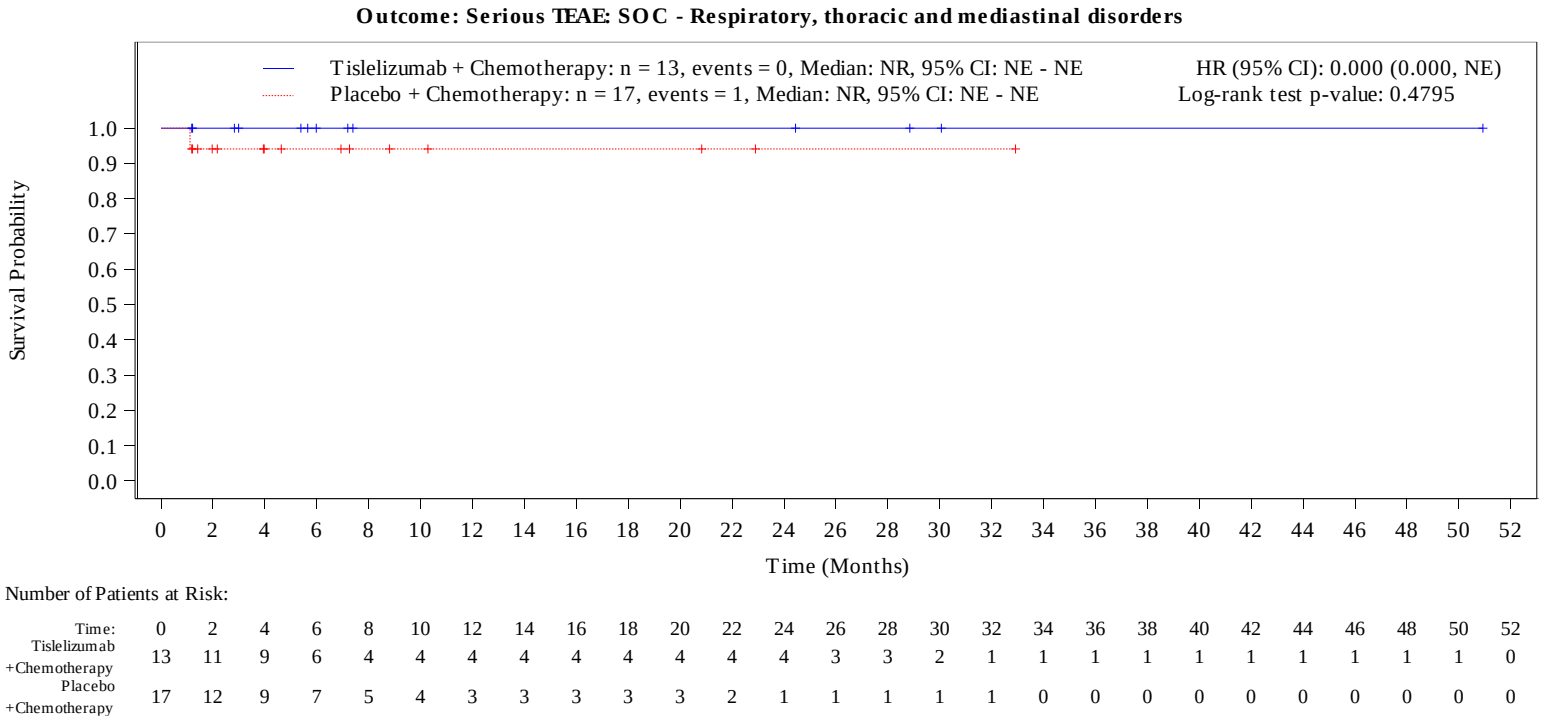
Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-4-km-aesocpt-ser-pop1-3y.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-4-km-aesocpt-ser-pop1-3y.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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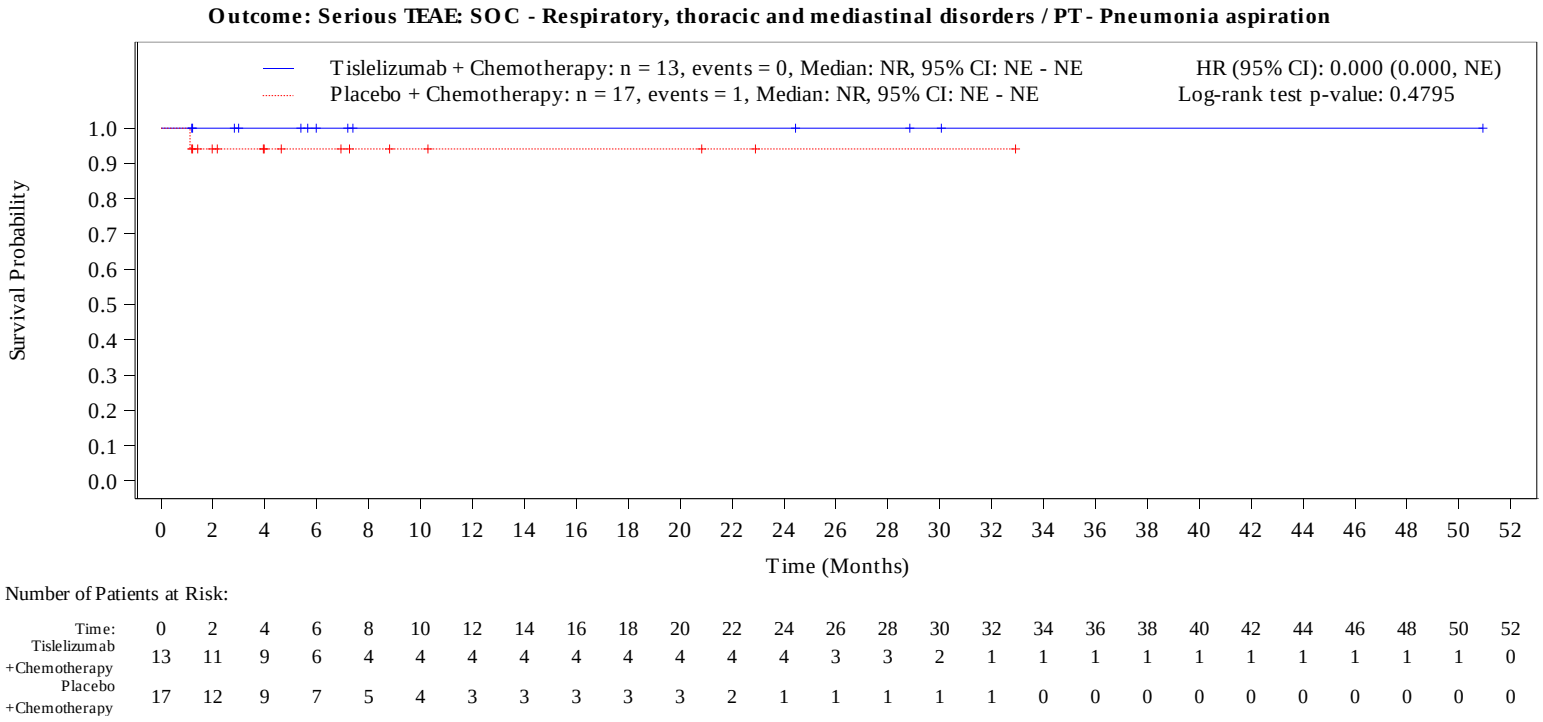
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesocpt.sas 21OCT2024 22:01 f-14-3-1-4-km-aesocpt-ser-pop1-3y.rtf

Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	7 (77.8)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	6 (66.7)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	2 (20.0)	--	--	--
1	6	5 (83.3)	--	7	2 (28.6)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	--	7	2 (28.6)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	3 (50.0)	--	7	1 (14.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	4 (44.4)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	6 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	3 (75.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-aesocpt-sub.sas 21OCT2024 08:41 t-14-3-1-2-2-2-1-s-aesocpt-sub-teae-pop1-3y.rtf

Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	6 (60.0)	--	--	--
1	6	3 (50.0)	--	7	3 (42.9)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	1 (25.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	2 (33.3)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/t-aesocpt-sub.sas 21OCT2024 08:41 t-14-3-1-2-2-3-1-s-aesocpt-sub-gr3-pop1-3y.rtf

Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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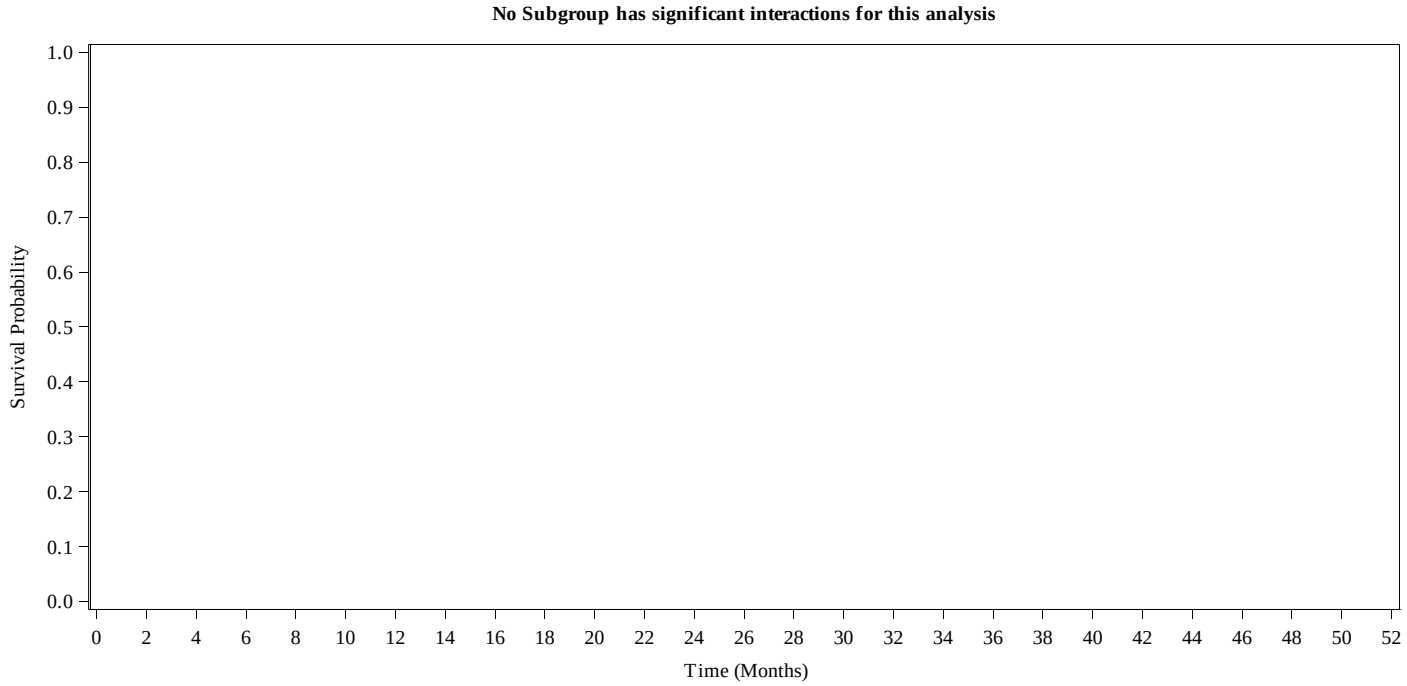
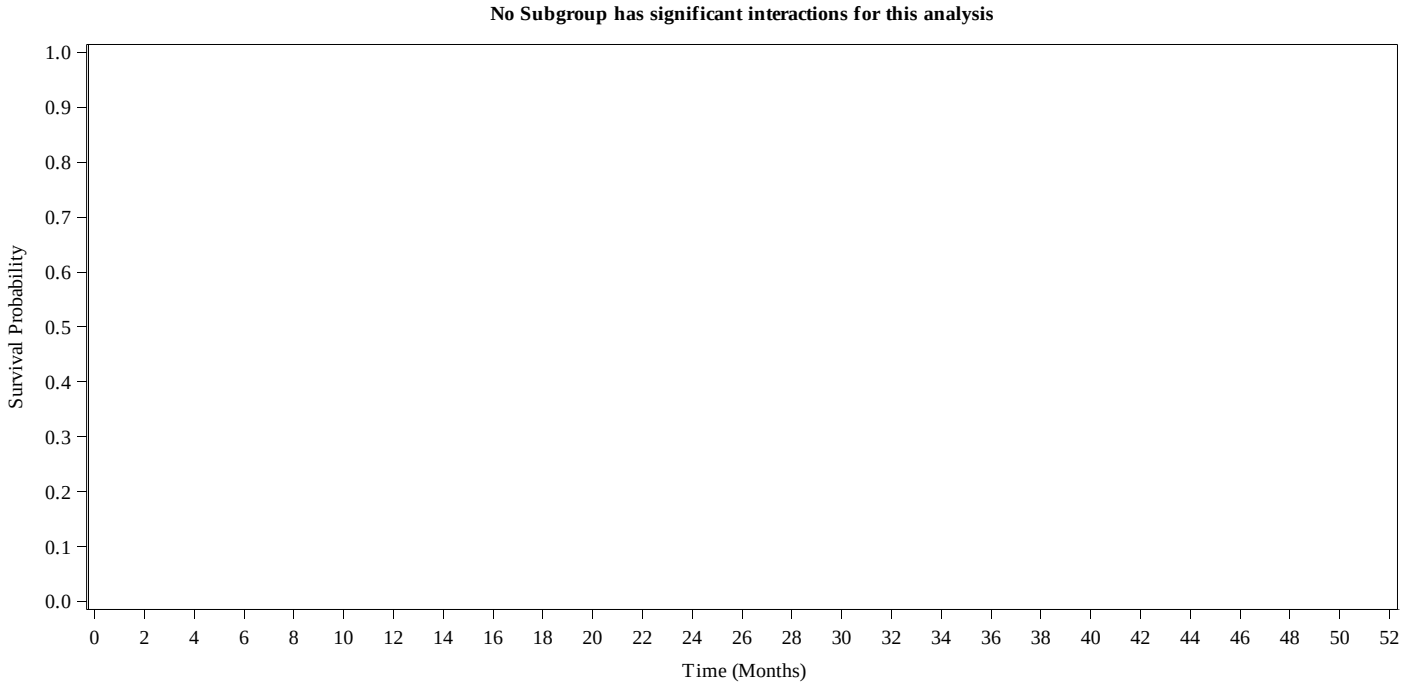
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



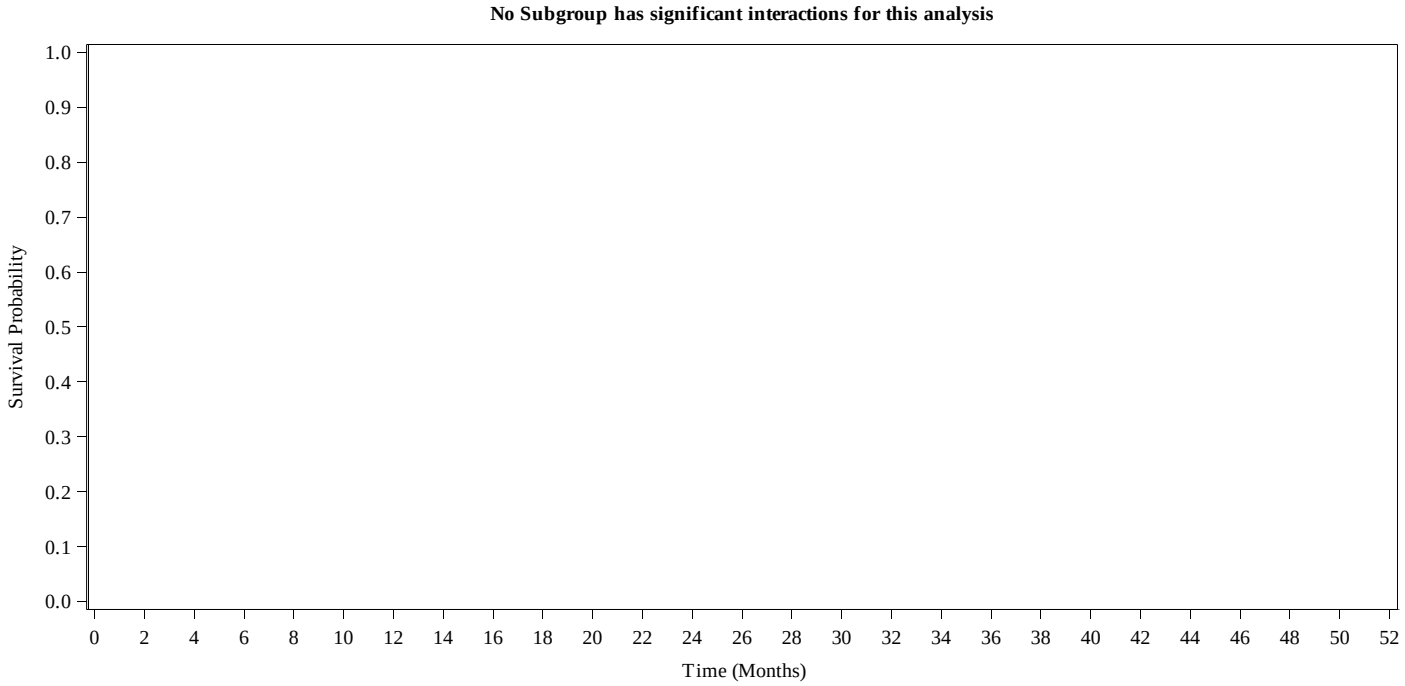
Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any imAE	13	5 (38.5)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.186 (0.261, 5.396)	0.8252
imAE of Grade 1 and 2	13	4 (30.8)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.081 (0.226, 5.165)	0.9220
imAE >= Grade 3	13	2 (15.4)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Serious imAE	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5930

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR of Grade 1 and 2	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR >= Grade 3	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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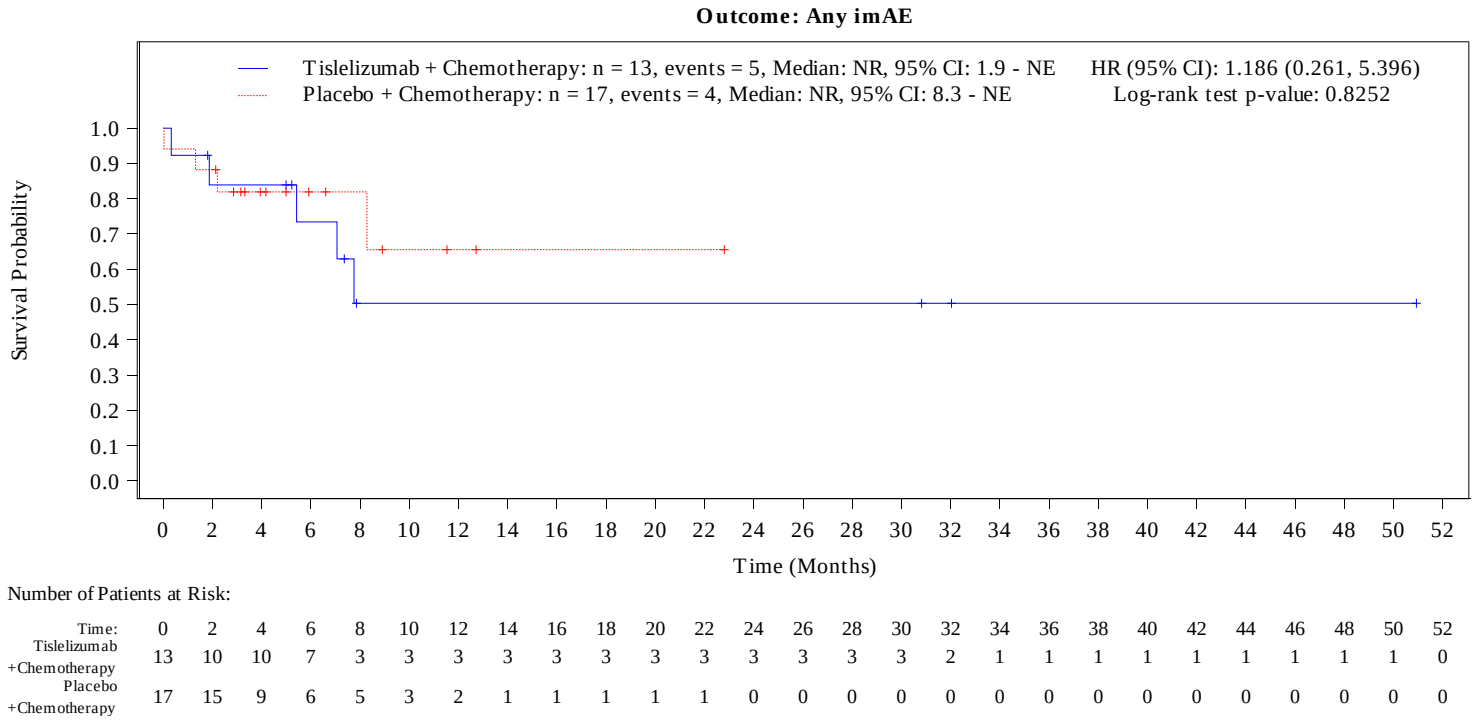
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	10	10	7	3	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	15	9	6	5	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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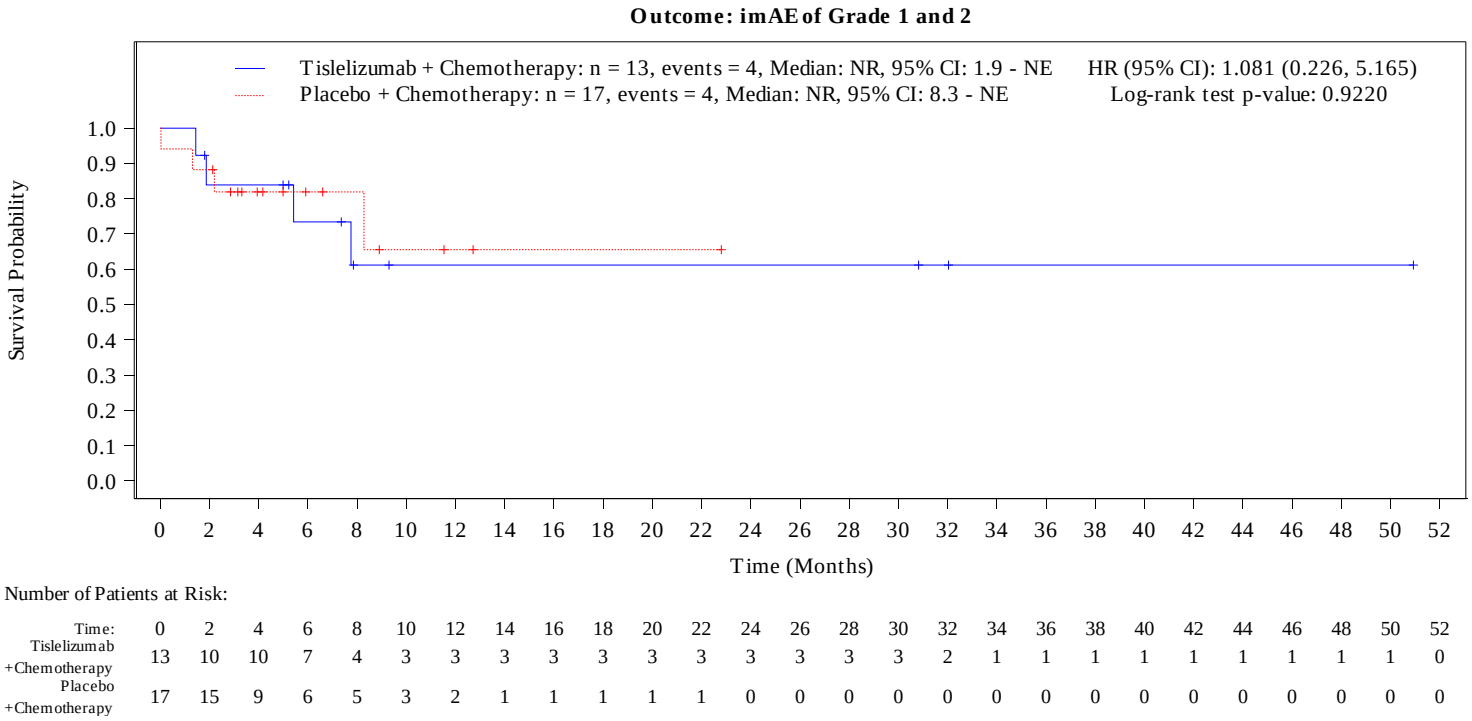
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	10	10	7	4	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	15	9	6	5	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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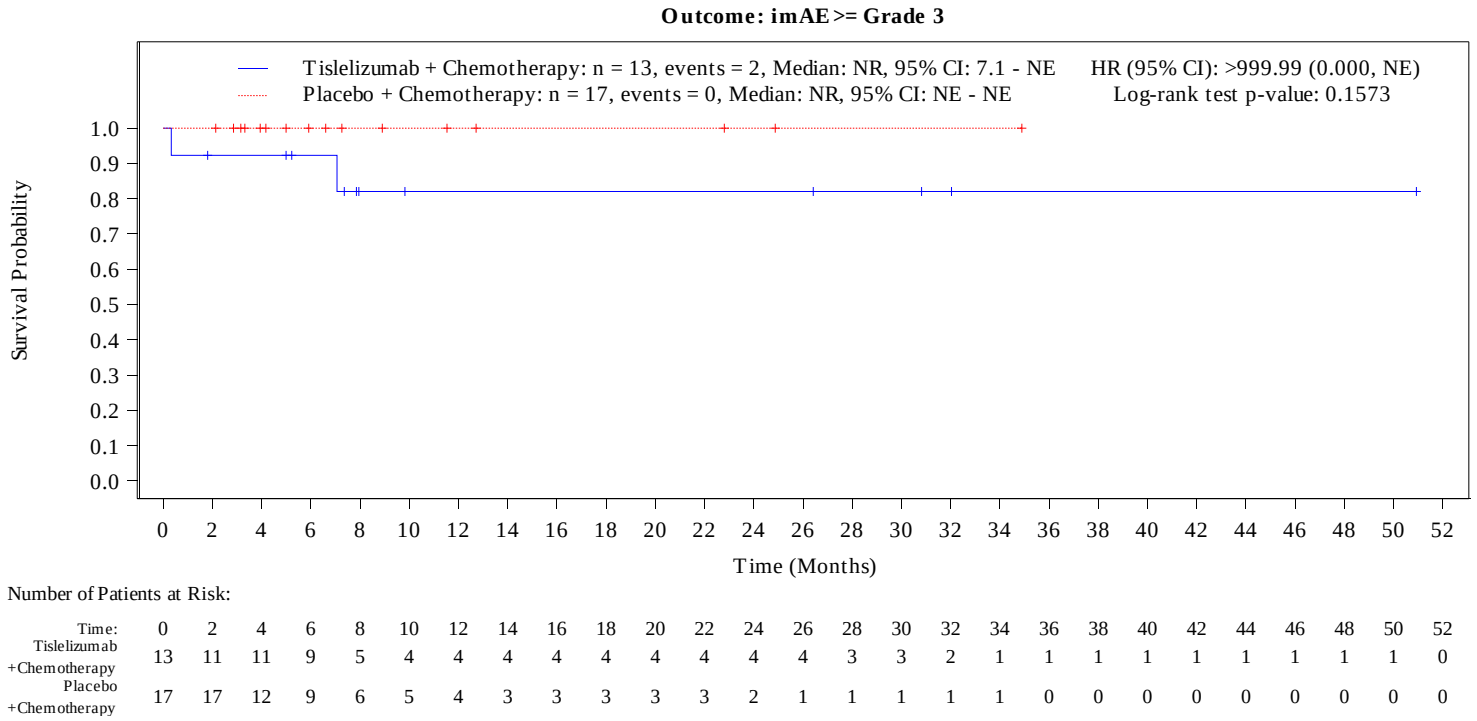
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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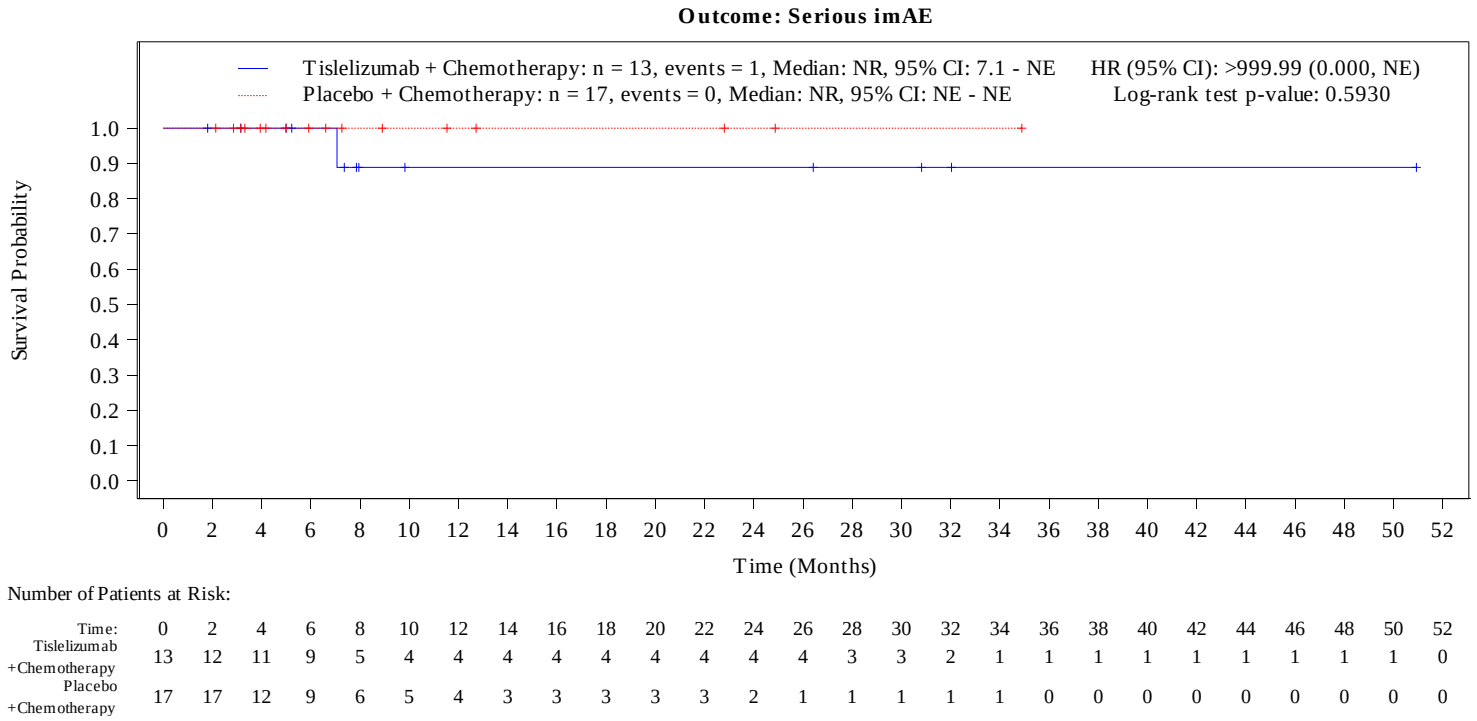
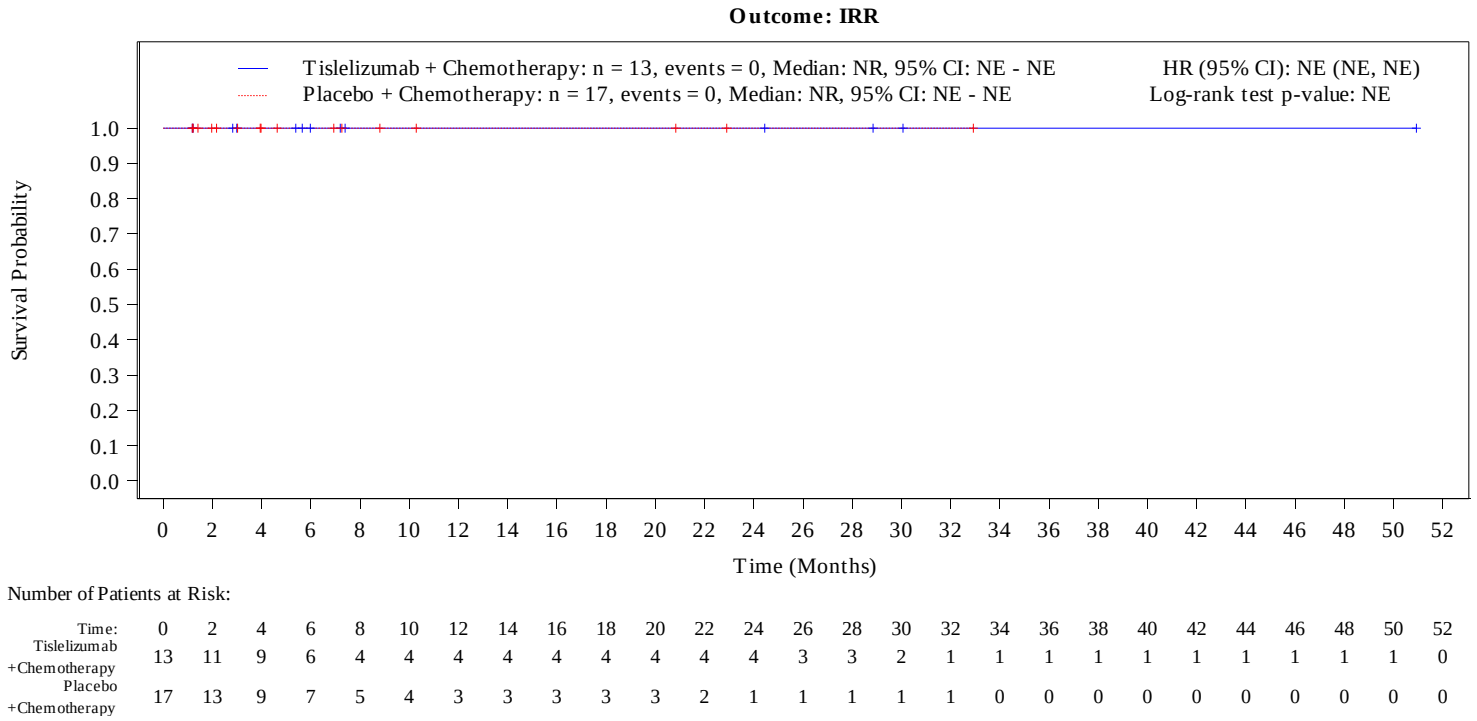
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesi.sas 21OCT2024 21:59 f-14-3-1-5-km-aesi-pop1-3y.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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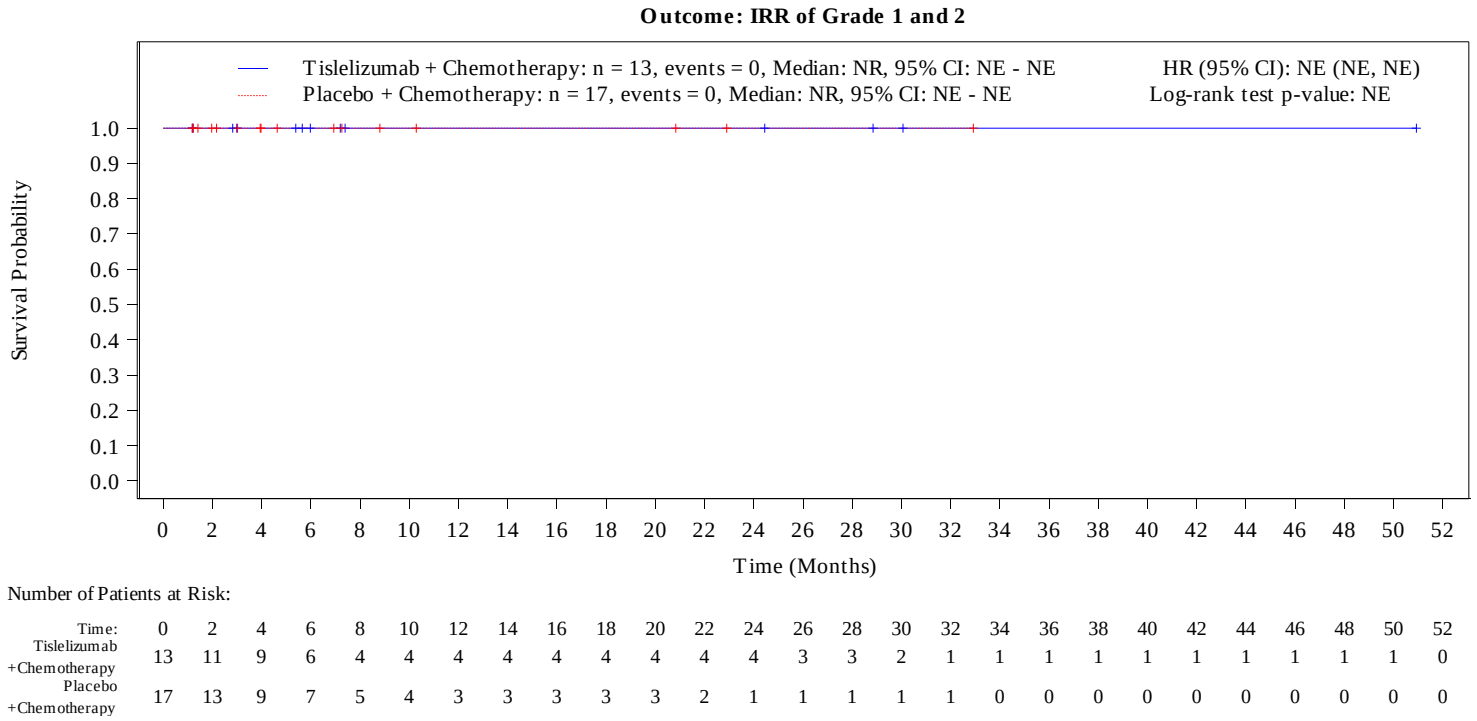
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

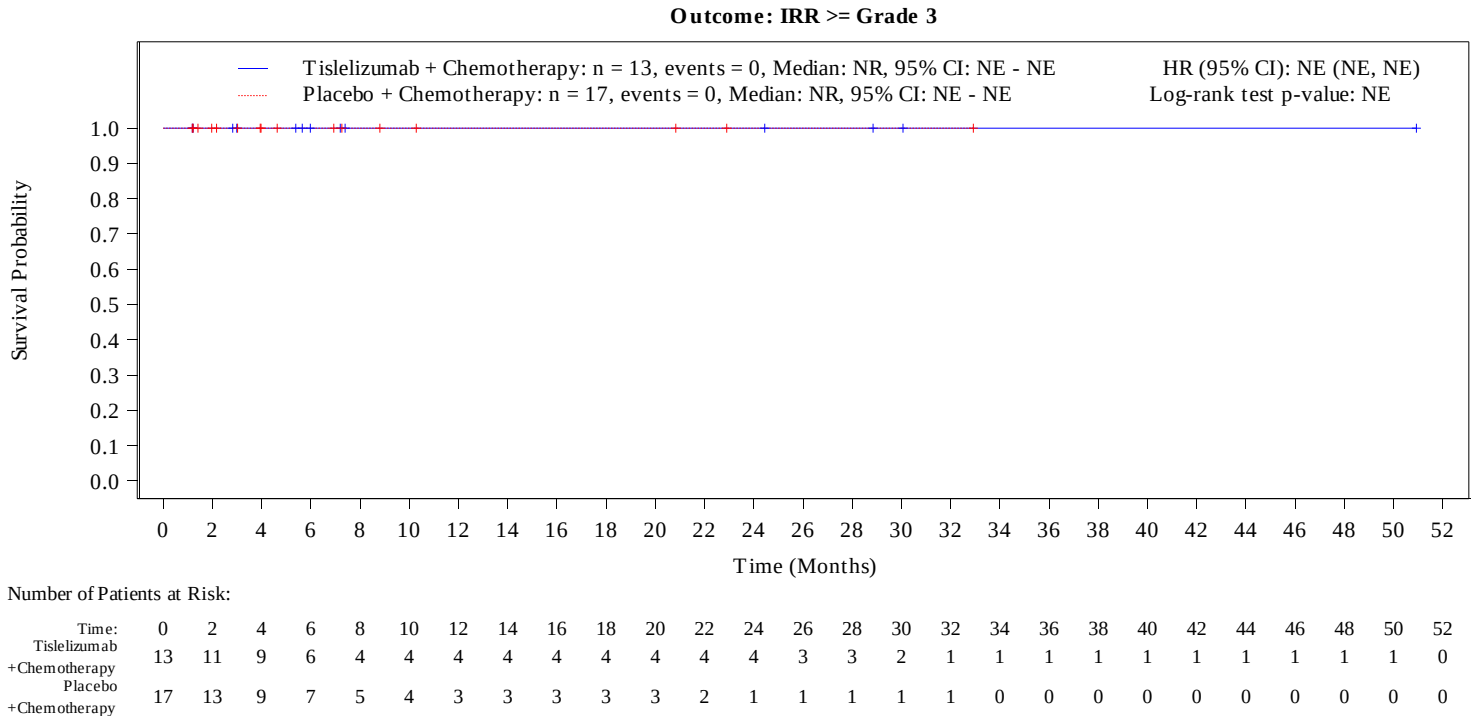


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

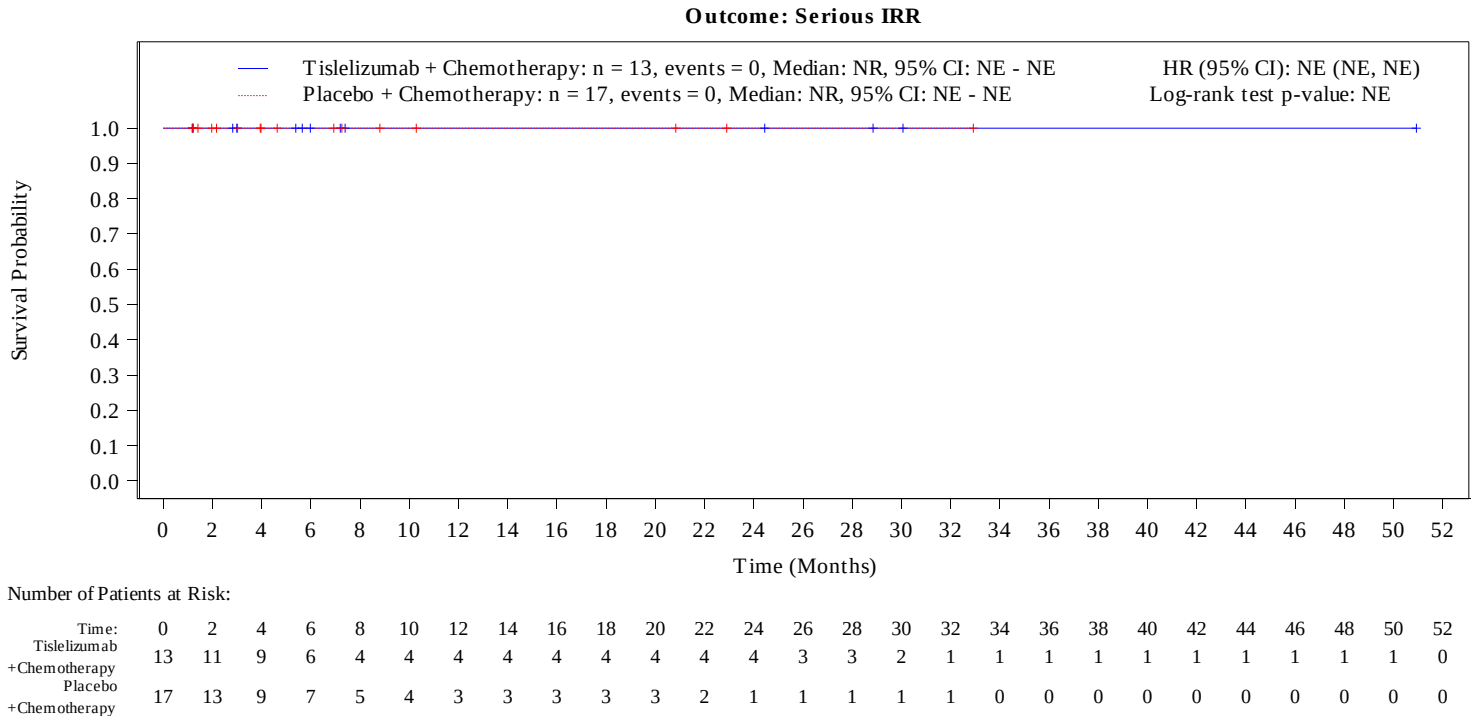
Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesi.sas 21OCT2024 21:59 f-14-3-1-5-km-aesi-pop1-3y.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q3/dev/pgm/tlfs/f-km-aesi.sas 21OCT2024 21:59 f-14-3-1-5-km-aesi-pop1-3y.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	3 (33.3)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	3 (33.3)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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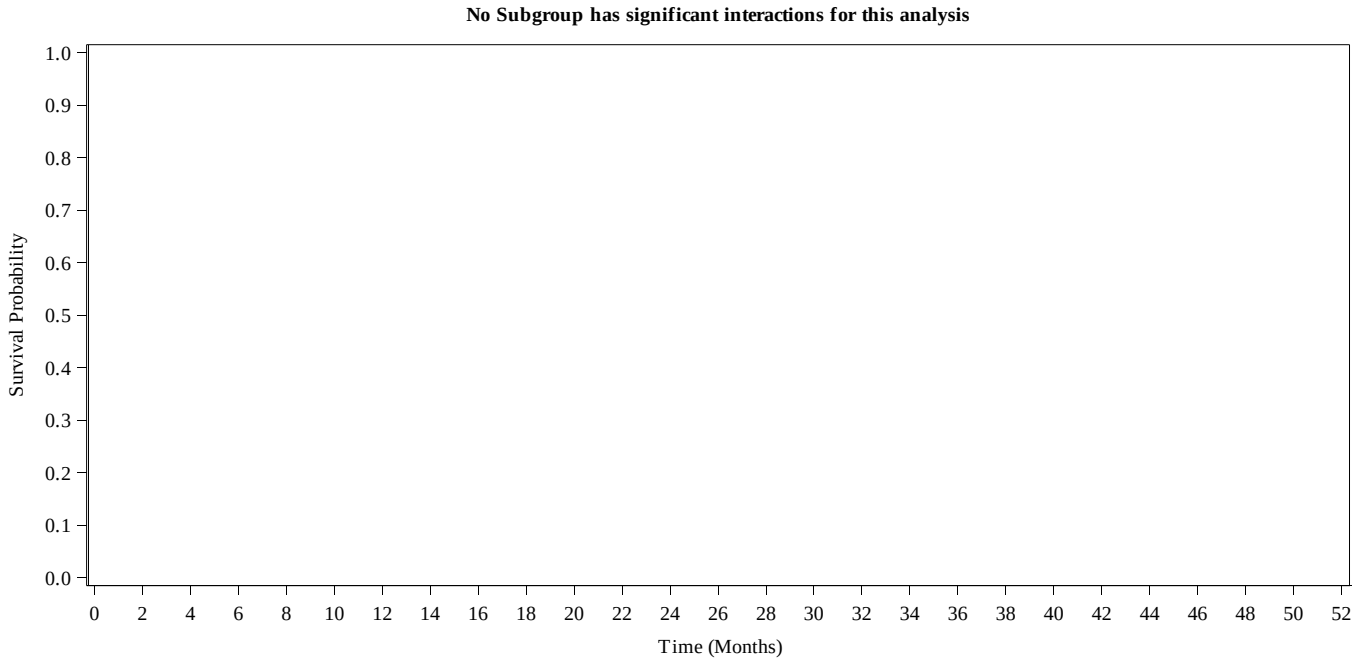
Figure 14.3.1.5.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Data cutoff: 24NOV2023. Data extraction: 28DEC2023.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Adverse events were graded for severity using CTCAE v4.03. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Number of Patients Randomized	13 (100.0)	17 (100.0)	30 (100.0)
Patients Randomized, But not Treated	0 (0.0)	0 (0.0)	0 (0.0)
Primary Reason for not Treated [a]			
Number of Patients Treated	13 (100.0)	17 (100.0)	30 (100.0)
Number of Patients Discontinued from Treatment	13 (100.0)	17 (100.0)	30 (100.0)

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
[a] Patients randomized but not treated with any treatment component.
[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.
[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.
[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.).
[e] Minimum study follow-up time is defined as a difference between the date of last patient's last visit and the date of last patient randomized.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Drug Discontinuation [b]			
Progressive Disease	7 (53.8)	12 (70.6)	19 (63.3)
Radiographic Progression	6 (46.2)	11 (64.7)	17 (56.7)
Clinical Progression	1 (7.7)	1 (5.9)	2 (6.7)
Withdrawal by Subject	3 (23.1)	2 (11.8)	5 (16.7)
Adverse Event	1 (7.7)	2 (11.8)	3 (10.0)
Study Terminated by Sponsor	1 (7.7)	0 (0.0)	1 (3.3)
Treatment-interruption [c]	1 (7.7)	0 (0.0)	1 (3.3)
Other	0 (0.0)	1 (5.9)	1 (3.3)
Number of Patients Remained on Treatment	0 (0.0)	0 (0.0)	0 (0.0)
Number of Patients Discontinued from Study	13 (100.0)	17 (100.0)	30 (100.0)

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.).

[e] Minimum study follow-up time is defined as a difference between the date of last patient's last visit and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Primary Reason for Study Discontinuation			
Death	7 (53.8)	12 (70.6)	19 (63.3)
Study Terminated by Sponsor	6 (46.2)	3 (17.6)	9 (30.0)
Lost to Follow-up	0 (0.0)	1 (5.9)	1 (3.3)
Withdrawal by Subject	0 (0.0)	1 (5.9)	1 (3.3)
Number of Patients Remained on Study	0 (0.0)	0 (0.0)	0 (0.0)
Study Follow-up Duration [d] (months)			
n	13	17	30
Mean (SD)	32.4 (18.89)	18.5 (17.14)	24.6 (18.94)
Median	26.5	9.8	19.8
Q1, Q3	19.1, 50.4	7.0, 23.8	8.0, 44.9
Min, Max	1.8, 57.5	2.2, 51.2	1.8, 57.5

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
[a] Patients randomized but not treated with any treatment component.
[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.
[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.
[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.).
[e] Minimum study follow-up time is defined as a difference between the date of last patient's last visit and the date of last patient randomized.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.1.2.1:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Minimum Study Follow-Up Time [e] (months)	47.9	47.3	47.3

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Percentages were based on N.

[a] Patients randomized but not treated with any treatment component.

[b] Reason for patients discontinued from treatment is the reason for treatment component whichever discontinued last. If tislelizumab and chemotherapy discontinued at the same date, the reason for discontinuation of tislelizumab will be presented.

[c] Patients with confirmed CR, PR or SD after 2 years of study treatment may stop the treatment.

[d] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.).

[e] Minimum study follow-up time is defined as a difference between the date of last patient's last visit and the date of last patient randomized.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Age (years)			
n	13	17	30
Mean (SD)	59.7 (7.48)	65.1 (7.94)	62.8 (8.08)
Median	60.0	66.0	62.5
Q1, Q3	57.0, 65.0	59.0, 72.0	58.0, 69.0
Min, Max	46, 69	47, 76	46, 76
Age Group, n (%)			
< 65 years	9 (69.2)	8 (47.1)	17 (56.7)
≥ 65 years	4 (30.8)	9 (52.9)	13 (43.3)
Sex, n (%)			
Female	4 (30.8)	6 (35.3)	10 (33.3)
Male	9 (69.2)	11 (64.7)	20 (66.7)
Region, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Asia (excluding Japan)	6 (46.2)	2 (11.8)	8 (26.7)
Japan	5 (38.5)	9 (52.9)	14 (46.7)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Race, n (%)			
Asian	11 (84.6)	11 (64.7)	22 (73.3)
Chinese	5 (38.5)	1 (5.9)	6 (20.0)
Japanese	5 (38.5)	9 (52.9)	14 (46.7)
Korean	1 (7.7)	1 (5.9)	2 (6.7)
White	2 (15.4)	5 (29.4)	7 (23.3)
American Indian or Alaska Native	0 (0.0)	1 (5.9)	1 (3.3)
Ethnicity, n (%)			
Hispanic or Latino	0 (0.0)	1 (5.9)	1 (3.3)
Not Hispanic or Latino	13 (100.0)	16 (94.1)	29 (96.7)
ECOG Status, n (%)			
0	7 (53.8)	10 (58.8)	17 (56.7)
1	6 (46.2)	7 (41.2)	13 (43.3)

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-dm.sas 14NOV2024 06:36 t-14-1-2-1-dm-pop1-cl.rtf

Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
BMI (kg/m^2)			
n	13	17	30
Mean (SD)	21.92 (3.553)	21.20 (3.497)	21.51 (3.479)
Median	21.63	20.91	21.40
Q1, Q3	21.10, 22.86	19.20, 23.31	20.20, 23.31
Min, Max	14.3, 28.3	15.9, 29.2	14.3, 29.2
Tobacco Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	9 (69.2)	12 (70.6)	21 (70.0)
Current	1 (7.7)	1 (5.9)	2 (6.7)
Alcohol Consumption, n (%)			
Never	3 (23.1)	4 (23.5)	7 (23.3)
Former	8 (61.5)	10 (58.8)	18 (60.0)
Current	2 (15.4)	2 (11.8)	4 (13.3)
Missing	0 (0.0)	1 (5.9)	1 (3.3)
Pooled Geographic Region per IRT, n (%)			
Asia	11 (84.6)	11 (64.7)	22 (73.3)
Rest of World	2 (15.4)	6 (35.3)	8 (26.7)

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Definitive Therapy per IRT, n (%)			
Yes	4 (30.8)	7 (41.2)	11 (36.7)
No	9 (69.2)	10 (58.8)	19 (63.3)

Source: ADSL. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group.
Percentages were based on N.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Time from Initial Diagnosis to Study Entry (months)			
n	13	17	30
Mean (SD)	8.30 (16.077)	8.16 (15.719)	8.22 (15.598)
Median	0.95	1.81	1.12
Q1, Q3	0.76, 12.48	0.82, 11.10	0.76, 12.09
Min, Max	0.5, 58.2	0.2, 65.7	0.2, 65.7
Primary Site of Esophageal Cancer, n (%)			
Cervical	0 (0.0)	3 (17.6)	3 (10.0)
Upper thoracic	5 (38.5)	4 (23.5)	9 (30.0)
Middle thoracic	4 (30.8)	5 (29.4)	9 (30.0)
Lower thoracic	4 (30.8)	5 (29.4)	9 (30.0)

Source: ADSL, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-dh.sas 14NOV2024 06:31 t-14-1-3-1-dh-pop1-cl.rtf

Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Histologic Grade, n (%)			
Gx - Grade cannot be assessed	5 (38.5)	8 (47.1)	13 (43.3)
G1 - Well-differentiated	1 (7.7)	2 (11.8)	3 (10.0)
G2 - Moderately-differentiated	6 (46.2)	6 (35.3)	12 (40.0)
G3 - Poorly differentiated	1 (7.7)	1 (5.9)	2 (6.7)
Histologic Type, n (%)			
Squamous Cell Carcinoma	13 (100.0)	17 (100.0)	30 (100.0)
Other [a]	0 (0.0)	0 (0.0)	0 (0.0)
Disease Stage at Diagnosis [b], n (%)			
Stage I (IA, IB)	1 (7.7)	1 (5.9)	2 (6.7)
Stage II (IIA, IIB)	1 (7.7)	2 (11.8)	3 (10.0)
Stage III (IIIA, IIIB, IIIC)	3 (23.1)	5 (29.4)	8 (26.7)
Stage IV	8 (61.5)	9 (52.9)	17 (56.7)

Source: ADSL, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Disease Status at Study Entry, n (%)			
Metastatic	12 (92.3)	15 (88.2)	27 (90.0)
Locally Advanced	1 (7.7)	2 (11.8)	3 (10.0)
Time from Metastatic Disease to Study Entry (months)			
n	12	15	27
Mean (SD)	1.30 (1.812)	3.51 (10.275)	2.53 (7.713)
Median	0.74	0.72	0.72
Q1, Q3	0.53, 1.33	0.33, 1.38	0.46, 1.35
Min, Max	0.3, 6.9	0.0, 40.6	0.0, 40.6
Number of Metastatic Sites at Study Entry, n (%)			
0	1 (7.7)	2 (11.8)	3 (10.0)
1	9 (69.2)	8 (47.1)	17 (56.7)
2	2 (15.4)	5 (29.4)	7 (23.3)
>2	1 (7.7)	2 (11.8)	3 (10.0)

Source: ADSL, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Locations of Metastases at Study Entry [c], n (%)			
Lymph Nodes	7 (53.8)	6 (35.3)	13 (43.3)
Lung	6 (46.2)	7 (41.2)	13 (43.3)
Liver	2 (15.4)	4 (23.5)	6 (20.0)
Bone	1 (7.7)	1 (5.9)	2 (6.7)
Brain	0 (0.0)	0 (0.0)	0 (0.0)
Peritoneum	0 (0.0)	0 (0.0)	0 (0.0)
Skin	0 (0.0)	0 (0.0)	0 (0.0)
Soft Tissue	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	6 (35.3)	6 (20.0)

Source: ADSL, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Description	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Target Lesions Sum of Diameter by Investigator (mm)			
n	13	15	28
Mean (SD)	30.95 (18.422)	54.19 (28.241)	43.40 (26.527)
Median	27.20	54.62	31.00
Q1, Q3	17.00, 43.20	27.00, 75.00	21.35, 62.36
Min, Max	10.4, 67.0	18.8, 109.0	10.4, 109.0
PD-L1 Status, n (%)			
PD-L1 Score < 10%	13 (100.0)	17 (100.0)	30 (100.0)

Source: ADSL, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
PD-L1 status is determined using VENTANA PD-L1 (SP263) Assay. Unknown refers to the patients without sample collection or not evaluable at baseline.
Study Entry date referred to randomization date in this study.
[a] Patient 086006-001 was randomized based on a pathological report stating the tumor was squamous cell carcinoma. After randomization, the histologic type of the tumor was confirmed to be 'Neuroendocrine tumor' in a new pathological report according to the biopsy performed before randomization.
[b] The disease stage at diagnosis for one patient was reclassified from Stage IV at the interim analysis to Stage III in the FDA 120-day safety update and subsequent analyses.
[c] A patient was counted only once within each category, but may be counted in multiple categories.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Patients with at Least One Prior Definitive Therapy, n (%) [a]	4 (30.8)	7 (41.2)	11 (36.7)
Definitive Radiotherapy with/without Chemotherapy	0 (0.0)	1 (5.9)	1 (3.3)
Definitive Surgery with/without Adjuvant/Neo-adjuvant Treatment	4 (30.8)	6 (35.3)	10 (33.3)
Time from End of Last Prior Anti-Cancer Therapy to Study Entry [b] (months)			
n	4	8	12
Mean (SD)	22.71 (23.656)	30.69 (58.484)	28.03 (48.422)
Median	13.27	9.82	10.12
Q1, Q3	9.56, 35.86	7.39, 18.07	7.39, 19.81
Min, Max	6.4, 57.9	0.6, 174.4	0.6, 174.4
Prior Anti-Cancer Systemic Therapy, n (%)	2 (15.4)	5 (29.4)	7 (23.3)
Platinum Based Prior Anti-Cancer Systemic Therapy			
Yes	2 (15.4)	5 (29.4)	7 (23.3)
No	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-pr-crs.sas 14NOV2024 06:37 t-14-1-5-1-pr-crs-pop1-cl.rtf

Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Treatment Setting of Prior Anti-Cancer Systemic Therapies, n (%) [a]			
Neo-adjuvant Setting	2 (15.4)	4 (23.5)	6 (20.0)
Adjuvant Setting	1 (7.7)	0 (0.0)	1 (3.3)
In Combination with Definitive Radiotherapy	0 (0.0)	2 (11.8)	2 (6.7)
Duration of Last Prior Anti-Cancer Systemic Therapy (months)			
n	2	5	7
Mean (SD)	1.81 (1.254)	2.24 (1.291)	2.12 (1.191)
Median	1.81	1.81	1.81
Q1, Q3	0.92, 2.69	1.58, 2.50	0.99, 2.69
Min, Max	0.9, 2.7	1.0, 4.3	0.9, 4.3

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-pr-crs.sas 14NOV2024 06:37 t-14-1-5-1-pr-crs-pop1-cl.rtf

Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Radiotherapy, n (%)	1 (7.7)	3 (17.6)	4 (13.3)
Site Irradiated, n (%) [a]			
Brain	0 (0.0)	1 (5.9)	1 (3.3)
Lung - left	0 (0.0)	0 (0.0)	0 (0.0)
Lung - right	0 (0.0)	0 (0.0)	0 (0.0)
Liver	0 (0.0)	0 (0.0)	0 (0.0)
Esophagus	0 (0.0)	1 (5.9)	1 (3.3)
Head and neck	0 (0.0)	0 (0.0)	0 (0.0)
Stomach	0 (0.0)	0 (0.0)	0 (0.0)
Retroperitoneum	1 (7.7)	0 (0.0)	1 (3.3)
Bone	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-pr-crs.sas 14NOV2024 06:37 t-14-1-5-1-pr-crs-pop1-cl.rtf

Table 14.1.5.1:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Prior Anti-Cancer Surgery, n (%)	4 (30.8)	7 (41.2)	11 (36.7)
Surgical Procedure, n (%) [a]			
Esophagectomy - Upper	0 (0.0)	3 (17.6)	3 (10.0)
Esophagectomy - Middle	2 (15.4)	1 (5.9)	3 (10.0)
Esophagectomy - Lower	2 (15.4)	2 (11.8)	4 (13.3)
Other	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
[a] A patient was counted only once within each category but may be counted in multiple categories.
[b] Study Entry date referred to randomization date in this study.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-pr-crs.sas 14NOV2024 06:37 t-14-1-5-1-pr-crs-pop1-cl.rtf

Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Prior Medication	7 (53.8)	8 (47.1)	15 (50.0)
Amides	2 (15.4)	1 (5.9)	3 (10.0)
Lidocaine	2 (15.4)	1 (5.9)	3 (10.0)
Third-Generation Cephalosporins	2 (15.4)	0 (0.0)	2 (6.7)
Cefditoren Pivoxil	1 (7.7)	0 (0.0)	1 (3.3)
Cefotaxime Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids	1 (7.7)	0 (0.0)	1 (3.3)
Tranexamic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Anesthetics, Local	1 (7.7)	0 (0.0)	1 (3.3)
Dyclonine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-cm.sas 14NOV2024 06:30 t-14-1-6-1-cm-prmed-pop1-cl.rtf

Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Anilides	1 (7.7)	1 (5.9)	2 (6.7)
Paracetamol	1 (7.7)	1 (5.9)	2 (6.7)
Benzodiazepine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Amoxicillin;clavulanic Acid	1 (7.7)	0 (0.0)	1 (3.3)
Contact Laxatives	1 (7.7)	0 (0.0)	1 (3.3)
Sennoside A+b Calcium	1 (7.7)	0 (0.0)	1 (3.3)
Fluoroquinolones	1 (7.7)	0 (0.0)	1 (3.3)
Levofloxacin	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
H2-Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Famotidine	1 (7.7)	0 (0.0)	1 (3.3)
Natural Opium Alkaloids	1 (7.7)	0 (0.0)	1 (3.3)
Hydromorphone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	0 (0.0)	1 (3.3)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	0 (0.0)	1 (3.3)
Aldioxa	1 (7.7)	0 (0.0)	1 (3.3)
Proton Pump Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Esomeprazole Sodium	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	1 (7.7)	2 (11.8)	3 (10.0)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Unspecified Herbal And Traditional Medicine	1 (7.7)	0 (0.0)	1 (3.3)
Ginkgo Biloba Extract	1 (7.7)	0 (0.0)	1 (3.3)
Vitamin B1, Plain	1 (7.7)	0 (0.0)	1 (3.3)
Cetotiamine	1 (7.7)	0 (0.0)	1 (3.3)
Acetic Acid Derivatives And Related Substances	0 (0.0)	2 (11.8)	2 (6.7)
Aceclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Ketorolac Tromethamine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	0 (0.0)	1 (5.9)	1 (3.3)
Candesartan	0 (0.0)	1 (5.9)	1 (3.3)
Dihydropyridine Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)
Electrolyte Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Magnesium Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	0 (0.0)	1 (5.9)	1 (3.3)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefazolin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	0 (0.0)	2 (11.8)	2 (6.7)
Dexamethasone Sodium Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Triamcinolone	0 (0.0)	1 (5.9)	1 (3.3)
Opioid Anesthetics	0 (0.0)	1 (5.9)	1 (3.3)
Fentanyl Citrate	0 (0.0)	1 (5.9)	1 (3.3)
Other Opioids	0 (0.0)	1 (5.9)	1 (3.3)
Tramadol Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccines	0 (0.0)	1 (5.9)	1 (3.3)
Pneumococcal Vaccine Conj 13v (Crm197)	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.6.1:
Prior Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions For Parenteral Nutrition	0 (0.0)	2 (11.8)	2 (6.7)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins	0 (0.0)	1 (5.9)	1 (3.3)
Vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Medication	13 (100.0)	17 (100.0)	30 (100.0)
Serotonin (5ht3) Antagonists	13 (100.0)	15 (88.2)	28 (93.3)
Palonosetron Hydrochloride	5 (38.5)	8 (47.1)	13 (43.3)
Granisetron	4 (30.8)	2 (11.8)	6 (20.0)
Netupitant;palonosetron	2 (15.4)	0 (0.0)	2 (6.7)
Ondansetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Tropisetron Hydrochloride	2 (15.4)	0 (0.0)	2 (6.7)
Ondansetron	1 (7.7)	5 (29.4)	6 (20.0)
Palonosetron	1 (7.7)	0 (0.0)	1 (3.3)
Tropisetron	1 (7.7)	1 (5.9)	2 (6.7)
Granisetron Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Sulfonamides, Plain	11 (84.6)	8 (47.1)	19 (63.3)
Furosemide	9 (69.2)	8 (47.1)	17 (56.7)
Torasemide	2 (15.4)	0 (0.0)	2 (6.7)
Indapamide	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	2 (11.8)	3 (10.0)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antiemetics	10 (76.9)	13 (76.5)	23 (76.7)
Aprepitant	7 (53.8)	6 (35.3)	13 (43.3)
Fosaprepitant Meglumine	2 (15.4)	8 (47.1)	10 (33.3)
Fosaprepitant	1 (7.7)	0 (0.0)	1 (3.3)
Prochlorperazine	1 (7.7)	1 (5.9)	2 (6.7)
Promethazine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine Hydrochloride;diprophylline	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)
Prochlorperazine Maleate	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Osmotically Acting Laxatives	9 (69.2)	8 (47.1)	17 (56.7)
Magnesium Oxide	6 (46.2)	6 (35.3)	12 (40.0)
Lactulose	2 (15.4)	1 (5.9)	3 (10.0)
Macrogol	1 (7.7)	0 (0.0)	1 (3.3)
Magnesium Hydroxide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Electrolyte Solutions	8 (61.5)	13 (76.5)	21 (70.0)
Potassium Chloride	6 (46.2)	5 (29.4)	11 (36.7)
Magnesium Sulfate	4 (30.8)	8 (47.1)	12 (40.0)
Calcium Chloride;potassium Chloride;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	1 (5.9)	2 (6.7)
Electrolyte Solutions [umbrella Term]	0 (0.0)	1 (5.9)	1 (3.3)
Potassium	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Phosphate	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Proton Pump Inhibitors	8 (61.5)	12 (70.6)	20 (66.7)
Omeprazole	4 (30.8)	1 (5.9)	5 (16.7)
Esomeprazole Sodium	2 (15.4)	0 (0.0)	2 (6.7)
Lansoprazole	2 (15.4)	2 (11.8)	4 (13.3)
Esomeprazole	1 (7.7)	2 (11.8)	3 (10.0)
Esomeprazole Magnesium	1 (7.7)	0 (0.0)	1 (3.3)
Pantoprazole	1 (7.7)	0 (0.0)	1 (3.3)
Dexlansoprazole	0 (0.0)	1 (5.9)	1 (3.3)
Omeprazole Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Pantoprazole Sodium Sesquihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Rabeprazole Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Vonoprazan Fumarate	0 (0.0)	3 (17.6)	3 (10.0)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Solutions Affecting The Electrolyte Balance	7 (53.8)	12 (70.6)	19 (63.3)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	3 (17.6)	5 (16.7)
Electrolytes Nos;glucose	2 (15.4)	1 (5.9)	3 (10.0)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	2 (15.4)	0 (0.0)	2 (6.7)
Sodium Chloride	2 (15.4)	7 (41.2)	9 (30.0)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Gluconate Monohydrate;glucose;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate;sodium Chloride;sodium Citrate Dihydrate	1 (7.7)	1 (5.9)	2 (6.7)
Glucose;sodium Chloride	1 (7.7)	2 (11.8)	3 (10.0)
Solutions Affecting The Electrolyte Balance	1 (7.7)	1 (5.9)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Chloride;sodium Lactate	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Calcium Chloride;magnesium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;potassium Chloride;sodium Chloride	0 (0.0)	1 (5.9)	1 (3.3)
Glucose;sodium Chloride;sodium Lactate	0 (0.0)	4 (23.5)	4 (13.3)
H2-Receptor Antagonists	6 (46.2)	2 (11.8)	8 (26.7)
Famotidine	3 (23.1)	1 (5.9)	4 (13.3)
Cimetidine	2 (15.4)	0 (0.0)	2 (6.7)
Lafutidine	1 (7.7)	0 (0.0)	1 (3.3)
Ranitidine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Propulsives	6 (46.2)	6 (35.3)	12 (40.0)
Metoclopramide Dihydrochloride	3 (23.1)	1 (5.9)	4 (13.3)
Domperidone	1 (7.7)	2 (11.8)	3 (10.0)
Metoclopramide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Mosapride Citrate	1 (7.7)	1 (5.9)	2 (6.7)
Alizapride	0 (0.0)	1 (5.9)	1 (3.3)
Antiemetics And Antinauseants	5 (38.5)	10 (58.8)	15 (50.0)
Metoclopramide	4 (30.8)	5 (29.4)	9 (30.0)
Metoclopramide Hydrochloride	1 (7.7)	5 (29.4)	6 (20.0)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Colony Stimulating Factors	5 (38.5)	2 (11.8)	7 (23.3)
Filgrastim	3 (23.1)	1 (5.9)	4 (13.3)
Peg Granulocyte Colony Stimulating Factor	2 (15.4)	0 (0.0)	2 (6.7)
Mecapegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Pegfilgrastim	1 (7.7)	0 (0.0)	1 (3.3)
Granulocyte Colony Stimulating Factor	0 (0.0)	1 (5.9)	1 (3.3)
Solutions Producing Osmotic Diuresis	5 (38.5)	7 (41.2)	12 (40.0)
Mannitol	5 (38.5)	7 (41.2)	12 (40.0)
Anilides	4 (30.8)	9 (52.9)	13 (43.3)
Paracetamol	4 (30.8)	9 (52.9)	13 (43.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Blood Substitutes And Perfusion Solutions	4 (30.8)	4 (23.5)	8 (26.7)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	4 (30.8)	4 (23.5)	8 (26.7)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	4 (30.8)	2 (11.8)	6 (20.0)
Amoxicillin;clavulanic Acid	2 (15.4)	0 (0.0)	2 (6.7)
Amoxicillin Trihydrate;clavulanate Potassium	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam	1 (7.7)	0 (0.0)	1 (3.3)
Piperacillin Sodium;tazobactam Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Ampicillin Sodium;sulbactam Sodium	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Contact Laxatives	4 (30.8)	8 (47.1)	12 (40.0)
Sennoside A+b	3 (23.1)	6 (35.3)	9 (30.0)
Bisacodyl	1 (7.7)	3 (17.6)	4 (13.3)
Sennoside A+b Calcium	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Picosulfate	1 (7.7)	4 (23.5)	5 (16.7)
Senna Alexandrina Extract	0 (0.0)	1 (5.9)	1 (3.3)
Fluoroquinolones	4 (30.8)	2 (11.8)	6 (20.0)
Levofloxacin	3 (23.1)	1 (5.9)	4 (13.3)
Ciprofloxacin	1 (7.7)	0 (0.0)	1 (3.3)
Ofloxacin	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Heparin Group	4 (30.8)	3 (17.6)	7 (23.3)
Heparin Calcium	2 (15.4)	0 (0.0)	2 (6.7)
Bemiparin	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Enoxaparin	0 (0.0)	1 (5.9)	1 (3.3)
Heparin Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Corticosteroids, Potent (Group Iii)	3 (23.1)	1 (5.9)	4 (13.3)
Betamethasone Butyrate Propionate	1 (7.7)	0 (0.0)	1 (3.3)
Halometasone	1 (7.7)	0 (0.0)	1 (3.3)
Mometasone Furoate	1 (7.7)	0 (0.0)	1 (3.3)
Betamethasone Valerate	0 (0.0)	1 (5.9)	1 (3.3)
Difluprednate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Dihydropyridine Derivatives	3 (23.1)	3 (17.6)	6 (20.0)
Cilnidipine	2 (15.4)	0 (0.0)	2 (6.7)
Amlodipine	1 (7.7)	2 (11.8)	3 (10.0)
Lercanidipine Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate	0 (0.0)	1 (5.9)	1 (3.3)
Imidazole And Triazole Derivatives	3 (23.1)	1 (5.9)	4 (13.3)
Clobetasol Propionate;ketoconazole	1 (7.7)	0 (0.0)	1 (3.3)
Clotrimazole	1 (7.7)	0 (0.0)	1 (3.3)
Econazole Nitrate	1 (7.7)	0 (0.0)	1 (3.3)
Lanoconazole	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Mucolytics	3 (23.1)	3 (17.6)	6 (20.0)
Acetylcysteine	2 (15.4)	0 (0.0)	2 (6.7)
Ambroxol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Bromhexine Hydrochloride	0 (0.0)	2 (11.8)	2 (6.7)
Carbocisteine	0 (0.0)	1 (5.9)	1 (3.3)
Other Plain Vitamin Preparations	3 (23.1)	1 (5.9)	4 (13.3)
Pyridoxine Hydrochloride	3 (23.1)	1 (5.9)	4 (13.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Potassium	3 (23.1)	2 (11.8)	5 (16.7)
Potassium Chloride	2 (15.4)	0 (0.0)	2 (6.7)
Potassium Aspartate	1 (7.7)	2 (11.8)	3 (10.0)
Potassium Gluconate	0 (0.0)	1 (5.9)	1 (3.3)
Solutions For Parenteral Nutrition	3 (23.1)	6 (35.3)	9 (30.0)
Amino Acids Nos;fats Nos;glucose	2 (15.4)	0 (0.0)	2 (6.7)
Dl-Alpha Tocopheryl Acetate;glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	2 (15.4)	0 (0.0)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetic Acid;alanine;arginine;aspartic Acid;calcium;calcium Chloride;chloride;glucose;glutamate Sodium;glycerol;glycine;glycine Max Seed Oil;histidine;isoleucine;lecithin;leucine;lysine Hydrochloride;magnesium;magnesium Sulfate;methionine;phenylalanine;phosphorus;potassium;potassium Chloride;proline;serine;sodium;sodium Acetate;sodium Glycerophosphate;sodium Hydroxide;threonine;tryptophan, L-;tyrosine;valine	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos	1 (7.7)	0 (0.0)	1 (3.3)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Glucose	1 (7.7)	2 (11.8)	3 (10.0)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-cm.sas 14NOV2024 06:30 t-14-1-7-1-cm-gen-pop1-cl.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)
Alanine;arginine;aspartic Acid;calcium Chloride;glucose Monohydrate;glutamic Acid;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate;methionine;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	0 (0.0)	2 (11.8)	2 (6.7)
Substituted Alkylamines	3 (23.1)	3 (17.6)	6 (20.0)
Dexchlorpheniramine Maleate	2 (15.4)	2 (11.8)	4 (13.3)
Chlorphenamine	1 (7.7)	0 (0.0)	1 (3.3)
Chlorphenamine Maleate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Unspecified Herbal And Traditional Medicine	3 (23.1)	5 (29.4)	8 (26.7)
Unspecified Herbal And Traditional Medicine	2 (15.4)	0 (0.0)	2 (6.7)
Angelica Sinensis Root;atractylodes Macrocephala, Rhizoma;cremastra Appendiculata Pseudobulb;epimedium Spp.;panax Ginseng Root;solanum Lyratum;sophora Flavescens Root	1 (7.7)	0 (0.0)	1 (3.3)
Animal Unspecified;borneol;cow Bezoar;fungi Nos;indigo;pearl	1 (7.7)	0 (0.0)	1 (3.3)
Angelica Dahurica Root;calcium Sulfate Dihydrate;chrysanthemum X Morifolium Flower;coptis Chinensis Rhizome;forsythia Suspensa Fruit;gardenia Jasminoides Fruit;glycyrrhiza Spp. Root With Rhizome;inula Japonica Inflorescence;ligusticum Chuanxiong Rhizome;mentha Canadensis Herb;phellodendron Chinense Bark;platycodon Grandiflorus Root;rheum Spp. Root With Rhizome;saposhnikovia Divaricata Root;schizonepeta Tenuifolia Spike;scutellaria Baicalensis Root;vitex Trifolia Fruit	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	0 (0.0)	1 (5.9)	1 (3.3)
Citrus Aurantium Pericarp;creosote;glycyrrhiza Spp. Root With Rhizome;phellodendron Spp. Stem Bark;senegalia Catechu Twig	0 (0.0)	1 (5.9)	1 (3.3)
Coptis Spp.;glycyrrhiza Spp.;panax Ginseng;pinellia Ternata;scutellaria Baicalensis;zingiber Officinale;ziziphus Jujuba	0 (0.0)	1 (5.9)	1 (3.3)
Glycine Max Seed Oil	0 (0.0)	1 (5.9)	1 (3.3)
Glycyrrhiza Spp. Root;paeonia Lactiflora Root	0 (0.0)	2 (11.8)	2 (6.7)
Isatis Tinctoria Root;lobelia Chinensis Herb;taraxacum Spp. Herb;viola Philippica Herb	0 (0.0)	1 (5.9)	1 (3.3)
Panax Ginseng Root;zanthoxylum Piperitum Pericarp;zingiber Officinale Processed Rhizome	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antiinfectives And Antiseptics For Local Oral Treatment	2 (15.4)	1 (5.9)	3 (10.0)
Chlorhexidine	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Antiinfectives And Antiseptics For Local Oral Treatment	0 (0.0)	1 (5.9)	1 (3.3)
Ascorbic Acid (Vitamin C), Plain	2 (15.4)	1 (5.9)	3 (10.0)
Ascorbic Acid	2 (15.4)	1 (5.9)	3 (10.0)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-cm.sas 14NOV2024 06:30 t-14-1-7-1-cm-gen-pop1-cl.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Brotizolam	1 (7.7)	2 (11.8)	3 (10.0)
Estazolam	1 (7.7)	0 (0.0)	1 (3.3)
Lorazepam	1 (7.7)	0 (0.0)	1 (3.3)
Midazolam	1 (7.7)	1 (5.9)	2 (6.7)
Alprazolam	0 (0.0)	3 (17.6)	3 (10.0)
Flunitrazepam	0 (0.0)	1 (5.9)	1 (3.3)
Phenazepam	0 (0.0)	1 (5.9)	1 (3.3)
Biguanides	2 (15.4)	2 (11.8)	4 (13.3)
Metformin	1 (7.7)	0 (0.0)	1 (3.3)
Metformin Hydrochloride	1 (7.7)	2 (11.8)	3 (10.0)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Vitamins	2 (15.4)	0 (0.0)	2 (6.7)
Combinations Of Vitamins	1 (7.7)	0 (0.0)	1 (3.3)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)
Corticosteroids For Local Oral Treatment	2 (15.4)	2 (11.8)	4 (13.3)
Dexamethasone	2 (15.4)	2 (11.8)	4 (13.3)
Triamcinolone	1 (7.7)	0 (0.0)	1 (3.3)
General Nutrients	2 (15.4)	2 (11.8)	4 (13.3)
General Nutrients	1 (7.7)	2 (11.8)	3 (10.0)
Nutrients Nos	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Insulins And Analogues For Injection, Fast-Acting	2 (15.4)	3 (17.6)	5 (16.7)
Insulin	2 (15.4)	1 (5.9)	3 (10.0)
Insulin Human	0 (0.0)	1 (5.9)	1 (3.3)
Insulin Lispro	0 (0.0)	1 (5.9)	1 (3.3)
Macrolides	2 (15.4)	0 (0.0)	2 (6.7)
Roxithromycin	2 (15.4)	0 (0.0)	2 (6.7)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	2 (15.4)	0 (0.0)	2 (6.7)
Entecavir	2 (15.4)	0 (0.0)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Opium Alkaloids And Derivatives	2 (15.4)	1 (5.9)	3 (10.0)
Dextromethorphan	1 (7.7)	0 (0.0)	1 (3.3)
Dextromethorphan Hydrobromide	1 (7.7)	1 (5.9)	2 (6.7)
Other Antihistamines For Systemic Use	2 (15.4)	1 (5.9)	3 (10.0)
Cyproheptadine	1 (7.7)	0 (0.0)	1 (3.3)
Ebastine	1 (7.7)	0 (0.0)	1 (3.3)
Mebhydrolin	1 (7.7)	0 (0.0)	1 (3.3)
Rupatadine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs For Constipation	2 (15.4)	2 (11.8)	4 (13.3)
Glycerol	1 (7.7)	1 (5.9)	2 (6.7)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	1 (7.7)	2 (11.8)	3 (10.0)
Linaclotide	0 (0.0)	1 (5.9)	1 (3.3)
Other Immunostimulants	2 (15.4)	1 (5.9)	3 (10.0)
Batilol	1 (7.7)	1 (5.9)	2 (6.7)
Leucogen	1 (7.7)	0 (0.0)	1 (3.3)
Penicillins With Extended Spectrum	2 (15.4)	1 (5.9)	3 (10.0)
Amoxicillin	2 (15.4)	0 (0.0)	2 (6.7)
Amoxicillin Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Preparations Inhibiting Uric Acid Production	2 (15.4)	3 (17.6)	5 (16.7)
Allopurinol	1 (7.7)	1 (5.9)	2 (6.7)
Febuxostat	1 (7.7)	3 (17.6)	4 (13.3)
Propionic Acid Derivatives	2 (15.4)	7 (41.2)	9 (30.0)
Dexketoprofen	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen	1 (7.7)	1 (5.9)	2 (6.7)
Loxoprofen Sodium	1 (7.7)	3 (17.6)	4 (13.3)
Flurbiprofen Axetil	0 (0.0)	1 (5.9)	1 (3.3)
Loxoprofen Sodium Dihydrate	0 (0.0)	1 (5.9)	1 (3.3)
Zaltoprofen	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Acetic Acid Derivatives And Related Substances	1 (7.7)	0 (0.0)	1 (3.3)
Diclofenac Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	1 (7.7)	0 (0.0)	1 (3.3)
Fluticasone Furoate;vilanterol Trifenatate	1 (7.7)	0 (0.0)	1 (3.3)
Alpha-Adrenoreceptor Antagonists	1 (7.7)	1 (5.9)	2 (6.7)
Silodosin	1 (7.7)	1 (5.9)	2 (6.7)
Amides	1 (7.7)	1 (5.9)	2 (6.7)
Lidocaine	1 (7.7)	0 (0.0)	1 (3.3)
Lidocaine Hydrochloride;prilocaine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Aminoalkyl Ethers	1 (7.7)	0 (0.0)	1 (3.3)
Diphenhydramine	1 (7.7)	0 (0.0)	1 (3.3)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	1 (7.7)	1 (5.9)	2 (6.7)
Cilnidipine;valsartan	1 (7.7)	0 (0.0)	1 (3.3)
Amlodipine Besilate;telmisartan	0 (0.0)	1 (5.9)	1 (3.3)
Antibacterials For Systemic Use	1 (7.7)	0 (0.0)	1 (3.3)
Antibiotics	1 (7.7)	0 (0.0)	1 (3.3)
Antibiotics	1 (7.7)	0 (0.0)	1 (3.3)
Nystatin	1 (7.7)	0 (0.0)	1 (3.3)
Rifampicin	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Antidotes	1 (7.7)	1 (5.9)	2 (6.7)
Glutathione	1 (7.7)	1 (5.9)	2 (6.7)
Antiinflammatory Preparations, Non-Steroids For Topical Use	1 (7.7)	1 (5.9)	2 (6.7)
Felbinac	1 (7.7)	0 (0.0)	1 (3.3)
Loxoprofen Sodium	0 (0.0)	1 (5.9)	1 (3.3)
Antipropulsives	1 (7.7)	1 (5.9)	2 (6.7)
Loperamide Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Appetite Stimulants	1 (7.7)	0 (0.0)	1 (3.3)
Megestrol	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzodiazepine Related Drugs	1 (7.7)	3 (17.6)	4 (13.3)
Zolpidem	1 (7.7)	0 (0.0)	1 (3.3)
Eszopiclone	0 (0.0)	2 (11.8)	2 (6.7)
Zolpidem Tartrate	0 (0.0)	2 (11.8)	2 (6.7)
Benzomorphan Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Pentazocine	1 (7.7)	0 (0.0)	1 (3.3)
Beta Blocking Agents, Non-Selective	1 (7.7)	0 (0.0)	1 (3.3)
Propranolol Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Beta Blocking Agents, Selective	1 (7.7)	2 (11.8)	3 (10.0)
Atenolol	1 (7.7)	0 (0.0)	1 (3.3)
Bisoprolol	1 (7.7)	1 (5.9)	2 (6.7)
Bisoprolol Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Calcium, Combinations With Vitamin D And/Or Other Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Calcium Carbonate;colecalciferol;magnesium Carbonate	1 (7.7)	0 (0.0)	1 (3.3)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	1 (7.7)	0 (0.0)	1 (3.3)
Almagate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid;rifampicin	1 (7.7)	0 (0.0)	1 (3.3)
Combinations Of Various Lipid Modifying Agents	1 (7.7)	0 (0.0)	1 (3.3)
Atorvastatin;ezetimibe	1 (7.7)	0 (0.0)	1 (3.3)
Corticosteroids, Very Potent (Group Iv)	1 (7.7)	1 (5.9)	2 (6.7)
Clobetasol Propionate	1 (7.7)	1 (5.9)	2 (6.7)
Corticosteroids, Weak (Group I)	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-cm.sas 14NOV2024 06:30 t-14-1-7-1-cm-gen-pop1-cl.rtf

Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Coxibs	1 (7.7)	1 (5.9)	2 (6.7)
Etoricoxib	1 (7.7)	0 (0.0)	1 (3.3)
Celecoxib	0 (0.0)	1 (5.9)	1 (3.3)
Diazepines, Oxazepines, Thiazepines And Oxepines	1 (7.7)	4 (23.5)	5 (16.7)
Quetiapine	1 (7.7)	0 (0.0)	1 (3.3)
Olanzapine	0 (0.0)	4 (23.5)	4 (13.3)
Quetiapine Fumarate	0 (0.0)	1 (5.9)	1 (3.3)
Enemas	1 (7.7)	0 (0.0)	1 (3.3)
Glycerol	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Enzymes	1 (7.7)	1 (5.9)	2 (6.7)
Bromelains;cysteine	1 (7.7)	0 (0.0)	1 (3.3)
Pronase;sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	1 (7.7)	4 (23.5)	5 (16.7)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	1 (7.7)	2 (11.8)	3 (10.0)
Carbohydrates Nos;electrolytes Nos;lipids Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	1 (5.9)	1 (3.3)
Fibrates	1 (7.7)	0 (0.0)	1 (3.3)
Bezafibrate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Heparins Or Heparinoids For Topical Use	1 (7.7)	0 (0.0)	1 (3.3)
Mucopolysaccharide Polysulfuric Acid Ester	1 (7.7)	0 (0.0)	1 (3.3)
Hmg Coa Reductase Inhibitors	1 (7.7)	3 (17.6)	4 (13.3)
Pravastatin	1 (7.7)	1 (5.9)	2 (6.7)
Simvastatin	1 (7.7)	1 (5.9)	2 (6.7)
Rosuvastatin	0 (0.0)	1 (5.9)	1 (3.3)
Hydrazides	1 (7.7)	0 (0.0)	1 (3.3)
Isoniazid	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	1 (7.7)	1 (5.9)	2 (6.7)
Insulin Human;insulin Human Injection, Isophane	1 (7.7)	0 (0.0)	1 (3.3)
Insulin Aspart;insulin Aspart Protamine (Crystalline)	0 (0.0)	1 (5.9)	1 (3.3)
Iron, Parenteral Preparations	1 (7.7)	2 (11.8)	3 (10.0)
Iron	1 (7.7)	0 (0.0)	1 (3.3)
Saccharated Iron Oxide	0 (0.0)	2 (11.8)	2 (6.7)
Leukotriene Receptor Antagonists	1 (7.7)	0 (0.0)	1 (3.3)
Montelukast	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Medical Gases	1 (7.7)	0 (0.0)	1 (3.3)
Oxygen	1 (7.7)	0 (0.0)	1 (3.3)
Natural Opium Alkaloids	1 (7.7)	6 (35.3)	7 (23.3)
Codeine	1 (7.7)	0 (0.0)	1 (3.3)
Codeine Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Hydromorphone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Morphine Sulfate	0 (0.0)	1 (5.9)	1 (3.3)
Naloxone Hydrochloride;oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone	0 (0.0)	1 (5.9)	1 (3.3)
Oxycodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Agents For Local Oral Treatment	1 (7.7)	6 (35.3)	7 (23.3)
Sodium Gualenate Hydrate	1 (7.7)	3 (17.6)	4 (13.3)
Benzydamine Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Diclofenac	0 (0.0)	1 (5.9)	1 (3.3)
Glycerol	0 (0.0)	1 (5.9)	1 (3.3)
Lidocaine	0 (0.0)	2 (11.8)	2 (6.7)
Other Analgesics And Antipyretics	1 (7.7)	1 (5.9)	2 (6.7)
Pregabalin	1 (7.7)	1 (5.9)	2 (6.7)
Other Antibiotics For Topical Use	1 (7.7)	2 (11.8)	3 (10.0)
Mupirocin	1 (7.7)	1 (5.9)	2 (6.7)
Gentamicin Sulfate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antidepressants	1 (7.7)	2 (11.8)	3 (10.0)
Mianserin	1 (7.7)	0 (0.0)	1 (3.3)
Trazodone	0 (0.0)	1 (5.9)	1 (3.3)
Trazodone Hydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Other Antidiarrheals	1 (7.7)	0 (0.0)	1 (3.3)
Racecadotril	1 (7.7)	0 (0.0)	1 (3.3)
Other Blood Glucose Lowering Drugs, Excl. Insulins	1 (7.7)	0 (0.0)	1 (3.3)
Repaglinide	1 (7.7)	0 (0.0)	1 (3.3)
Other Dermatologicals	1 (7.7)	0 (0.0)	1 (3.3)
Camphor;methyl Salicylate	1 (7.7)	0 (0.0)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs Affecting Bone Structure And Mineralization	1 (7.7)	0 (0.0)	1 (3.3)
Denosumab	1 (7.7)	0 (0.0)	1 (3.3)
Other Drugs For Functional Gastrointestinal Disorders	1 (7.7)	1 (5.9)	2 (6.7)
Dimeticone	1 (7.7)	0 (0.0)	1 (3.3)
Simeticone	0 (0.0)	1 (5.9)	1 (3.3)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (7.7)	1 (5.9)	2 (6.7)
Sucralfate	1 (7.7)	0 (0.0)	1 (3.3)
Sodium Alginate	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Drugs For Treatment Of Tuberculosis	1 (7.7)	0 (0.0)	1 (3.3)
Ethambutol	1 (7.7)	0 (0.0)	1 (3.3)
Pyrazinamide	1 (7.7)	0 (0.0)	1 (3.3)
Other Hypnotics And Sedatives	1 (7.7)	2 (11.8)	3 (10.0)
Doxepin Hydrochloride	1 (7.7)	0 (0.0)	1 (3.3)
Suvorexant	0 (0.0)	2 (11.8)	2 (6.7)
Other Intestinal Adsorbents	1 (7.7)	1 (5.9)	2 (6.7)
Montmorillonite	1 (7.7)	0 (0.0)	1 (3.3)
Gelatin Tannate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Nervous System Drugs	1 (7.7)	0 (0.0)	1 (3.3)
Mecobalamin	1 (7.7)	0 (0.0)	1 (3.3)
Other Throat Preparations	1 (7.7)	0 (0.0)	1 (3.3)
Benzydamine	1 (7.7)	0 (0.0)	1 (3.3)
Other Viral Vaccines	1 (7.7)	2 (11.8)	3 (10.0)
Covid-19 Vaccine Mrna (Mrna 1273)	1 (7.7)	0 (0.0)	1 (3.3)
Tozinameran	0 (0.0)	2 (11.8)	2 (6.7)
Phenothiazines With Aliphatic Side-Chain	1 (7.7)	3 (17.6)	4 (13.3)
Chlorpromazine Hydrochloride	1 (7.7)	1 (5.9)	2 (6.7)
Chlorpromazine	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Piperazine Derivatives	1 (7.7)	0 (0.0)	1 (3.3)
Levocetirizine	1 (7.7)	0 (0.0)	1 (3.3)
Platelet Aggregation Inhibitors Excl. Heparin	1 (7.7)	2 (11.8)	3 (10.0)
Acetylsalicylate Lysine	1 (7.7)	1 (5.9)	2 (6.7)
Acetylsalicylic Acid	0 (0.0)	1 (5.9)	1 (3.3)
Pyrazolones	1 (7.7)	0 (0.0)	1 (3.3)
Metamizole	1 (7.7)	0 (0.0)	1 (3.3)
Second-Generation Cephalosporins	1 (7.7)	1 (5.9)	2 (6.7)
Cefaclor	1 (7.7)	0 (0.0)	1 (3.3)
Cefuroxime	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Selective Beta-2-Adrenoreceptor Agonists	1 (7.7)	1 (5.9)	2 (6.7)
Bambuterol	1 (7.7)	0 (0.0)	1 (3.3)
Tulobuterol	0 (0.0)	1 (5.9)	1 (3.3)
Selective Serotonin Reuptake Inhibitors	1 (7.7)	0 (0.0)	1 (3.3)
Sertraline	1 (7.7)	0 (0.0)	1 (3.3)
Third-Generation Cephalosporins	1 (7.7)	2 (11.8)	3 (10.0)
Ceftriaxone Sodium	1 (7.7)	0 (0.0)	1 (3.3)
Cefcapene Pivoxil Hydrochloride Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Cefoperazone	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Tonics	1 (7.7)	0 (0.0)	1 (3.3)
Inosine;sodium Chloride	1 (7.7)	0 (0.0)	1 (3.3)
Vitamins	1 (7.7)	1 (5.9)	2 (6.7)
Ascorbic Acid;biotin;cocarboxylase Tetrahydrate;colecalciferol;cyanocobalamin;dexpanthenol;dl-Alpha Tocopherol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Vitamins Nos	1 (7.7)	0 (0.0)	1 (3.3)
Ace Inhibitors, Plain	0 (0.0)	2 (11.8)	2 (6.7)
Perindopril	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids	0 (0.0)	1 (5.9)	1 (3.3)
Fenoterol Hydrobromide;ipratropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)
Aldose Reductase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Epalrestat	0 (0.0)	1 (5.9)	1 (3.3)
Aldosterone Antagonists	0 (0.0)	2 (11.8)	2 (6.7)
Spironolactone	0 (0.0)	2 (11.8)	2 (6.7)
Alpha Glucosidase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Voglibose	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Amino Acids And Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Ademetionine	0 (0.0)	1 (5.9)	1 (3.3)
Antidiarrheal Microorganisms	0 (0.0)	3 (17.6)	3 (10.0)
Antidiarrheal Microorganisms	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (5.9)	1 (3.3)
Bacillus Subtilis;lactomin	0 (0.0)	1 (5.9)	1 (3.3)
Antiseptics	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate;sodium Gualenate Hydrate	0 (0.0)	1 (5.9)	1 (3.3)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	0 (0.0)	1 (5.9)	1 (3.3)
Cimetropium Bromide	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Benzamides	0 (0.0)	1 (5.9)	1 (3.3)
Sulpiride	0 (0.0)	1 (5.9)	1 (3.3)
Beta Blocking Agents	0 (0.0)	1 (5.9)	1 (3.3)
Timolol	0 (0.0)	1 (5.9)	1 (3.3)
Bioflavonoids	0 (0.0)	1 (5.9)	1 (3.3)
Diosmin;hesperidin	0 (0.0)	1 (5.9)	1 (3.3)
Bisphosphonates	0 (0.0)	1 (5.9)	1 (3.3)
Zoledronic Acid	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Butyrophenone Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Haloperidol	0 (0.0)	2 (11.8)	2 (6.7)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Calcium	0 (0.0)	1 (5.9)	1 (3.3)
Carbamide Products	0 (0.0)	1 (5.9)	1 (3.3)
Urea	0 (0.0)	1 (5.9)	1 (3.3)
Carbapenems	0 (0.0)	2 (11.8)	2 (6.7)
Meropenem	0 (0.0)	1 (5.9)	1 (3.3)
Meropenem Trihydrate	0 (0.0)	1 (5.9)	1 (3.3)

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Percentages were based on N.
Concomitant medications include medications that either
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Combinations Of Oral Blood Glucose Lowering Drugs	0 (0.0)	1 (5.9)	1 (3.3)
Metformin Hydrochloride;sitagliptin Phosphate Monohydrate	0 (0.0)	1 (5.9)	1 (3.3)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dermatologicals	0 (0.0)	1 (5.9)	1 (3.3)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	0 (0.0)	4 (23.5)	4 (13.3)
Linagliptin	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate	0 (0.0)	1 (5.9)	1 (3.3)
Sitagliptin Phosphate Monohydrate	0 (0.0)	2 (11.8)	2 (6.7)
Diphenylmethane Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Hydroxyzine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Direct Factor Xa Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Apixaban	0 (0.0)	1 (5.9)	1 (3.3)
First-Generation Cephalosporins	0 (0.0)	1 (5.9)	1 (3.3)
Cefradine	0 (0.0)	1 (5.9)	1 (3.3)
Insulins And Analogues For Injection, Long-Acting	0 (0.0)	1 (5.9)	1 (3.3)
Insulin Glargine Biosimilar 1	0 (0.0)	1 (5.9)	1 (3.3)
Iron Trivalent, Oral Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Ferric Pyrophosphate	0 (0.0)	1 (5.9)	1 (3.3)

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Liver Therapy	0 (0.0)	2 (11.8)	2 (6.7)
Cysteine Hydrochloride;glycine;glycyrrhizic Acid, Ammonium Salt	0 (0.0)	1 (5.9)	1 (3.3)
Ornithine Aspartate	0 (0.0)	1 (5.9)	1 (3.3)
Polyene Phosphatidylcholine	0 (0.0)	1 (5.9)	1 (3.3)
Melatonin Receptor Agonists	0 (0.0)	1 (5.9)	1 (3.3)
Ramelteon	0 (0.0)	1 (5.9)	1 (3.3)
Other Aminoglycosides	0 (0.0)	1 (5.9)	1 (3.3)
Amikacin	0 (0.0)	1 (5.9)	1 (3.3)
Other Antianemic Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Darbepoetin Alfa	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Concomitant medications include medications that either
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Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Antibacterials	0 (0.0)	1 (5.9)	1 (3.3)
Fosfomycin	0 (0.0)	1 (5.9)	1 (3.3)
Other Antiepileptics	0 (0.0)	1 (5.9)	1 (3.3)
Lacosamide	0 (0.0)	1 (5.9)	1 (3.3)
Levetiracetam	0 (0.0)	1 (5.9)	1 (3.3)
Other Antimigraine Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Flunarizine Dihydrochloride	0 (0.0)	1 (5.9)	1 (3.3)
Other Antipruritics	0 (0.0)	1 (5.9)	1 (3.3)
Crotamiton	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Other Blood Products	0 (0.0)	1 (5.9)	1 (3.3)
Blood, Whole	0 (0.0)	1 (5.9)	1 (3.3)
Other Centrally Acting Agents	0 (0.0)	1 (5.9)	1 (3.3)
Baclofen	0 (0.0)	1 (5.9)	1 (3.3)
Other Emollients And Protectives	0 (0.0)	2 (11.8)	2 (6.7)
Mucopolysaccharide Polysulfuric Acid Ester	0 (0.0)	2 (11.8)	2 (6.7)
Other Irrigating Solutions	0 (0.0)	1 (5.9)	1 (3.3)
Mannitol;sorbitol	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Peripheral Opioid Receptor Antagonists	0 (0.0)	1 (5.9)	1 (3.3)
Naldemedine Tosilate	0 (0.0)	1 (5.9)	1 (3.3)
Phenylpiperidine Derivatives	0 (0.0)	2 (11.8)	2 (6.7)
Fentanyl Citrate	0 (0.0)	2 (11.8)	2 (6.7)
Preparations Increasing Uric Acid Excretion	0 (0.0)	1 (5.9)	1 (3.3)
Benzbromarone	0 (0.0)	1 (5.9)	1 (3.3)
Preparations With No Effect On Uric Acid Metabolism	0 (0.0)	1 (5.9)	1 (3.3)
Colchicine	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Concomitant medications include medications that either
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Proteinase Inhibitors	0 (0.0)	1 (5.9)	1 (3.3)
Camostat Mesilate	0 (0.0)	1 (5.9)	1 (3.3)
Sodium	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Chloride	0 (0.0)	2 (11.8)	2 (6.7)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic (Monohydrate)	0 (0.0)	1 (5.9)	1 (3.3)
Soft Paraffin And Fat Products	0 (0.0)	1 (5.9)	1 (3.3)
White Soft Paraffin	0 (0.0)	1 (5.9)	1 (3.3)
Stomatological Preparations	0 (0.0)	1 (5.9)	1 (3.3)
Sodium Bicarbonate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Sulfonylureas	0 (0.0)	1 (5.9)	1 (3.3)
Gliclazide	0 (0.0)	1 (5.9)	1 (3.3)
Triazole Derivatives	0 (0.0)	1 (5.9)	1 (3.3)
Fluconazole	0 (0.0)	1 (5.9)	1 (3.3)
Various Alimentary Tract And Metabolism Products	0 (0.0)	2 (11.8)	2 (6.7)
Borneol;cow Bezoar;musk;pearl;potassium Nitrate;realgar;sodium Borate Decahydrate;zingiber Officinale Rhizome	0 (0.0)	1 (5.9)	1 (3.3)
Zinc Acetate	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Disulfide	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.1:
Concomitant Medication
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Vitamin B12 (Cyanocobalamin And Analogues)	0 (0.0)	2 (11.8)	2 (6.7)
Cyanocobalamin	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin B12 Nos	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D And Analogues	0 (0.0)	2 (11.8)	2 (6.7)
Colecalciferol	0 (0.0)	1 (5.9)	1 (3.3)
Vitamin D Nos	0 (0.0)	1 (5.9)	1 (3.3)
Xanthines	0 (0.0)	1 (5.9)	1 (3.3)
Theophylline	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on/after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Concomitant Systemically Administered Corticosteroids/Immunosuppressive Drug During the Study	10 (76.9)	14 (82.4)	24 (80.0)
Patients with at Least One Concomitant Systemically Administered Corticosteroids Drugs	10 (76.9)	14 (82.4)	24 (80.0)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Glucocorticoids	10 (76.9)	14 (82.4)	24 (80.0)
Dexamethasone	6 (46.2)	8 (47.1)	14 (46.7)
Dexamethasone Sodium Phosphate	2 (15.4)	5 (29.4)	7 (23.3)
Methylprednisolone	2 (15.4)	1 (5.9)	3 (10.0)
Betamethasone	1 (7.7)	1 (5.9)	2 (6.7)
Betamethasone Sodium Phosphate	1 (7.7)	1 (5.9)	2 (6.7)
Hydrocortisone	1 (7.7)	0 (0.0)	1 (3.3)
Prednisolone	1 (7.7)	2 (11.8)	3 (10.0)
Prednisone	1 (7.7)	0 (0.0)	1 (3.3)
Methylprednisolone Sodium Succinate	0 (0.0)	1 (5.9)	1 (3.3)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.7.2:
Systemically Administered Corticosteroids/Immunosuppressants During the Study
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)	Total (N = 30) n (%)
Patients with at Least One Immunosuppressive Drugs	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADCM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: ATC, Anatomical Therapeutic Chemical.
Percentages were based on N.
systemic corticosteroid/immunosuppressant received between the first dose of study drug and up to 90 days after last dose will be summarized.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
Medication are sorted by decreasing frequency of ATC class then descending frequency of preferred name within ATC class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Overall Survival [a]			
n	13	17	30
Mean (SD)	32.42 (18.886)	18.53 (17.144)	24.55 (18.942)
Median	26.48	9.76	19.83
Q1, Q3	19.12, 50.43	6.97, 23.82	7.98, 44.88
Min, Max	1.8, 57.5	2.2, 51.2	1.8, 57.5
Progression-Free Survival [b]			
n	13	17	30
Mean (SD)	16.88 (20.143)	8.74 (11.786)	12.27 (16.168)
Median	5.68	4.44	5.52
Q1, Q3	2.83, 29.08	2.07, 8.54	2.76, 9.95
Min, Max	1.8, 56.7	1.2, 46.1	1.2, 56.7

Source: ADSL, ADTTE, ADEFPRE, ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Investigator Tumor Assessment [c]			
n	13	17	30
Mean (SD)	16.94 (20.108)	8.64 (10.945)	12.24 (15.840)
Median	5.68	4.44	5.60
Q1, Q3	4.04, 29.08	2.66, 8.54	2.76, 9.95
Min, Max	1.3, 56.7	1.2, 42.1	1.2, 56.7
EORTC-QLQ-C30 [d]			
n	13	17	30
Mean (SD)	11.30 (15.998)	8.09 (9.253)	9.48 (12.480)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 57.5	1.0, 32.9	0.0, 57.5

Source: ADSL, ADTTE, ADEFPRE, ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
EORTC-QLQ-OES18 [d]			
n	13	17	30
Mean (SD)	11.30 (15.998)	8.09 (9.253)	9.48 (12.480)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 57.5	1.0, 32.9	0.0, 57.5
EQ-5D VAS [d]			
n	13	17	30
Mean (SD)	11.30 (15.998)	8.09 (9.253)	9.48 (12.480)
Median	5.68	4.80	5.24
Q1, Q3	2.79, 7.79	1.54, 9.26	1.54, 9.26
Min, Max	0.0, 57.5	1.0, 32.9	0.0, 57.5

Source: ADSL, ADTTE, ADEFPRE, ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.1.8.2:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Endpoint (Months)	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Total (N = 30)
Safety for TEAEs [a]			
n	13	17	30
Mean (SD)	13.90 (16.718)	8.12 (9.018)	10.63 (13.000)
Median	5.98	4.63	5.52
Q1, Q3	2.99, 24.44	2.17, 8.80	2.83, 10.28
Min, Max	1.2, 57.5	1.2, 32.9	1.2, 57.5
Safety for imAEs [b]			
n	13	17	30
Mean (SD)	15.71 (16.333)	9.80 (9.227)	12.36 (12.893)
Median	7.95	6.60	7.31
Q1, Q3	5.22, 26.41	3.94, 11.53	4.17, 12.71
Min, Max	1.8, 57.5	2.1, 34.9	1.8, 57.5

Source: ADSL, ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event; imAE, immune-mediated adverse event.

[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.

[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Number of Patients		
Death, n (%)	7 (53.8)	12 (70.6)
Censored, n (%)	6 (46.2)	5 (29.4)
Lost to Follow-up	0 (0.0)	1 (5.9)
Withdrawal by Subject	0 (0.0)	1 (5.9)
Study Discontinuation Due to Other Reasons	6 (46.2)	3 (17.6)
Two-sided Stratified Log-rank Test p-value [a]	0.4086	
Stratified Hazard Ratio (95% CI) [b]	0.611 (0.189, 1.975)	
Unstratified Hazard Ratio (95% CI) [c]	0.477 (0.186, 1.224)	

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death, patients will be censored at the date that the patient was last known to be alive.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Overall Survival (months)		
Median (95% CI)	26.5 (16.4, NE)	11.8 (7.0, 46.1)
Q1 (95% CI)	19.1 (1.8, 26.5)	8.0 (2.2, 11.8)
Q3 (95% CI)	NR (26.0, NE)	46.1 (11.8, NE)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	92.3 (56.6, 98.9)	88.2 (60.6, 96.9)
6 Months (95% CI)	92.3 (56.6, 98.9)	82.4 (54.7, 93.9)
9 Months (95% CI)	84.6 (51.2, 95.9)	69.1 (40.7, 85.9)
12 Months (95% CI)	84.6 (51.2, 95.9)	48.4 (22.5, 70.2)
18 Months (95% CI)	76.9 (44.2, 91.9)	48.4 (22.5, 70.2)

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death, patients will be censored at the date that the patient was last known to be alive.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
24 Months (95% CI)	61.5 (30.8, 81.8)	27.6 (8.7, 50.9)
30 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)
36 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)
42 Months (95% CI)	46.2 (19.2, 69.6)	27.6 (8.7, 50.9)
48 Months (95% CI)	46.2 (19.2, 69.6)	13.8 (1.1, 41.7)
54 Months (95% CI)	46.2 (19.2, 69.6)	NR (NE, NE)
60 Months (95% CI)	NR (NE, NE)	NR (NE, NE)
Follow-up Time (months)		
Median (95% CI)	50.6 (44.2, NE)	44.9 (43.3, NE)

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

In absence of death, patients will be censored at the date that the patient was last known to be alive.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Overall survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula. Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Primary OS analysis: Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[b] Primary OS estimand summary measure: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] Unstratified OS sensitivity analysis: Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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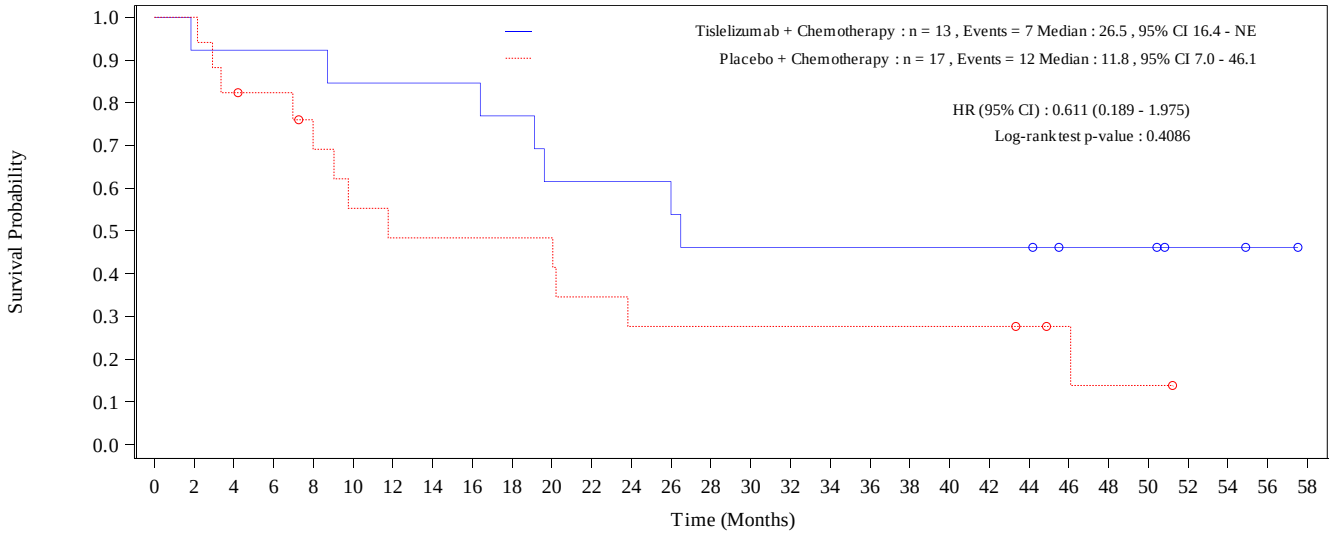
Figure 14.2.1.1:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
Tislelizumab +Chemotherapy	13	13	12	12	12	12	12	12	12	11	11	11	11	11	11	11	11	10	10	10	8	8	8	8	8	8	7	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	4	4	4	4	4	2	2	2	2	1	1	1	0
Placebo +Chemotherapy	17	17	17	15	14	13	13	12	10	10	8	8	7	7	7	7	7	7	7	7	7	5	5	5	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	2	2	1	1	1	1	0	0	0	0	0	0	0

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE, not estimable; NR, not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.
Hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy. (yes vs no) per IRT.
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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	4 (44.4)	NR (8.7, NE)	8	4 (50.0)	20.0 (3.4, NE)	0.531 (0.131, 2.147)	0.3668
Age >= 65	4	3 (75.0)	26.2 (1.8, NE)	9	8 (88.9)	9.8 (2.2, NE)	0.666 (0.167, 2.663)	0.5631
Interaction								0.8457
Sex								
Male	9	6 (66.7)	26.0 (1.8, NE)	11	8 (72.7)	20.0 (2.9, NE)	0.697 (0.240, 2.023)	0.5050
Female	4	1 (25.0)	NR (19.1, NE)	6	4 (66.7)	9.8 (7.0, NE)	0.192 (0.021, 1.750)	0.1043
Interaction								0.2755

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	19.6 (8.7, 26.5)	10	7 (70.0)	9.8 (2.9, NE)	0.731 (0.243, 2.199)	0.5756
1	6	1 (16.7)	NR (1.8, NE)	7	5 (71.4)	20.2 (2.2, NE)	0.168 (0.019, 1.471)	0.0696
Interaction								0.1455

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	NR (8.7, NE)	7	6 (85.7)	9.8 (2.2, NE)	0.445 (0.089, 2.219)	0.3105
No	9	5 (55.6)	26.5 (1.8, NE)	10	6 (60.0)	20.0 (2.9, NE)	0.535 (0.159, 1.792)	0.3033
Interaction								0.8687

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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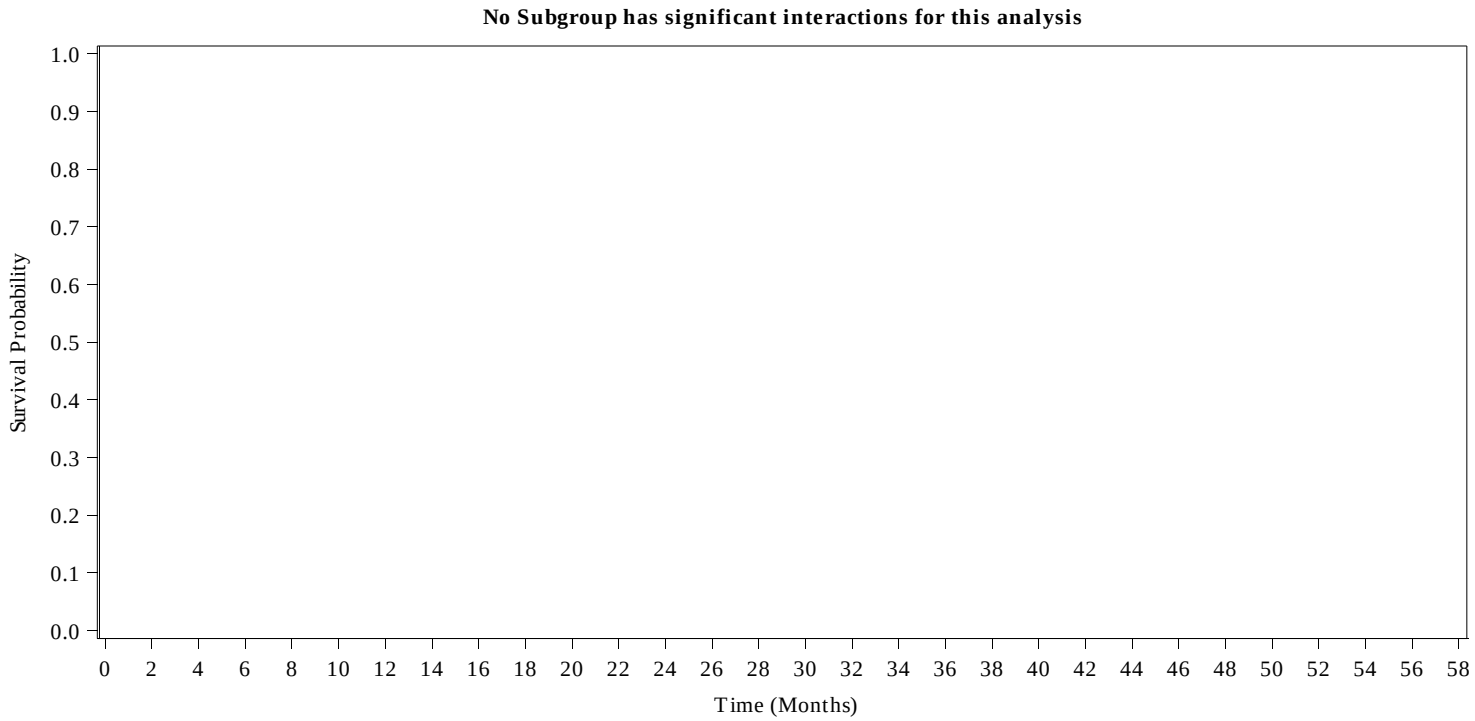
Figure 14.2.1.1.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression-Free Survival		
Events, n (%)	9 (69.2)	15 (88.2)
Progressive Disease	8 (61.5)	14 (82.4)
Death	1 (7.7)	1 (5.9)
Censored, n (%)	4 (30.8)	2 (11.8)
New Anti-Cancer Therapy	2 (15.4)	1 (5.9)
No PD/Death [a]	2 (15.4)	1 (5.9)
Study Terminated by Sponsor	2 (15.4)	1 (5.9)
Two-sided Stratified Log-rank Test p-value [b]	0.2759	
Stratified Hazard Ratio (95% CI) [c]	0.580 (0.216, 1.557)	
Unstratified Hazard Ratio (95% CI) [d]	0.550 (0.238, 1.273)	

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression Free Survival (months)		
Median (95% CI)	6.9 (2.8, NE)	4.4 (1.3, 8.5)
Q1 (95% CI)	5.6 (1.8, 5.7)	2.1 (1.2, 4.1)
Q3 (95% CI)	NR (5.7, NE)	8.5 (4.4, NE)

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	76.9 (44.2, 91.9)	58.8 (32.5, 77.8)
6 Months (95% CI)	51.3 (21.9, 74.6)	35.3 (14.5, 57.0)
9 Months (95% CI)	34.2 (10.7, 59.8)	23.5 (7.3, 44.9)
12 Months (95% CI)	34.2 (10.7, 59.8)	17.6 (4.3, 38.3)
18 Months (95% CI)	34.2 (10.7, 59.8)	17.6 (4.3, 38.3)
24 Months (95% CI)	34.2 (10.7, 59.8)	17.6 (4.3, 38.3)
30 Months (95% CI)	25.6 (6.2, 51.3)	17.6 (4.3, 38.3)
36 Months (95% CI)	25.6 (6.2, 51.3)	17.6 (4.3, 38.3)
42 Months (95% CI)	25.6 (6.2, 51.3)	17.6 (4.3, 38.3)
48 Months (95% CI)	25.6 (6.2, 51.3)	0.0 (NE, NE)
54 Months (95% CI)	25.6 (6.2, 51.3)	0.0 (NE, NE)
60 Months (95% CI)	NR (NE, NE)	0.0 (NE, NE)

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Percentages were based on N.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley. Progression free rates (cumulative probabilities of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

[a] Patients ongoing without PD and with no Post-baseline assessments are counted in 'No PD/Death Ongoing Without Events' category.

[b] Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only .

[c] Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment arm as a covariate and stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[d] Unstratified Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on unstratified Cox regression model only including treatment arm as a covariate. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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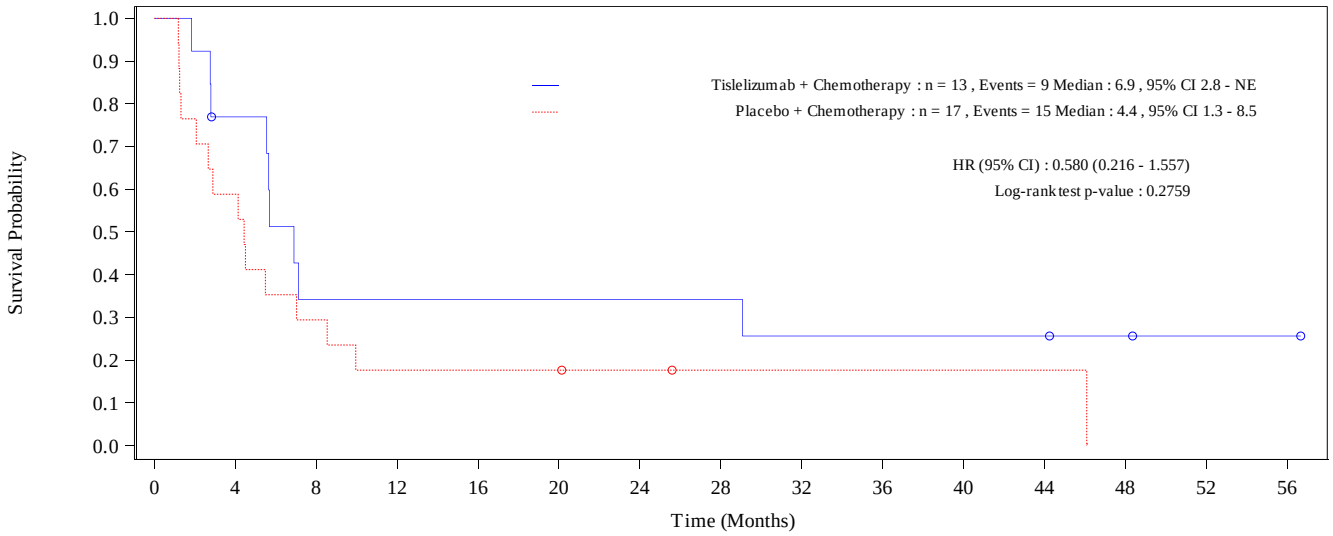
Figure 14.2.4.1:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57
Tislelizumab +Chemotherapy	13	13	12	9	9	9	6	5	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	1	1	1	1	1	1	1	1	0	
Placebo +Chemotherapy	17	17	13	10	10	7	6	6	5	4	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE, not estimable.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
Hazard ratio (Tislelizumab+Chemotherapy vs. Placebo+Chemotherapy) was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	6 (66.7)	5.7 (2.8, NE)	8	6 (75.0)	3.5 (1.2, NE)	0.525 (0.159, 1.730)	0.2813
Age >= 65	4	3 (75.0)	6.9 (1.8, NE)	9	9 (100.0)	4.5 (1.2, 10.0)	1.095 (0.272, 4.409)	0.8987
Interaction								0.5117
Sex								
Male	9	7 (77.8)	5.7 (1.8, 7.1)	11	10 (90.9)	4.1 (1.2, 10.0)	1.032 (0.376, 2.836)	0.9514
Female	4	2 (50.0)	NR (2.8, NE)	6	5 (83.3)	4.5 (1.2, NE)	0.213 (0.025, 1.842)	0.1226
Interaction								0.1549

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	6 (85.7)	5.7 (2.8, NE)	10	9 (90.0)	4.5 (1.3, 7.0)	0.988 (0.338, 2.886)	0.9824
1	6	3 (50.0)	NR (1.8, NE)	7	6 (85.7)	2.9 (1.2, NE)	0.330 (0.080, 1.358)	0.1081
Interaction								0.1898

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	5.7 (2.8, NE)	7	6 (85.7)	4.5 (1.2, NE)	0.436 (0.087, 2.183)	0.2995
No	9	7 (77.8)	6.9 (1.8, NE)	10	9 (90.0)	4.3 (1.2, 8.5)	0.562 (0.199, 1.585)	0.2695
Interaction								0.8229

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable; NR, not reached.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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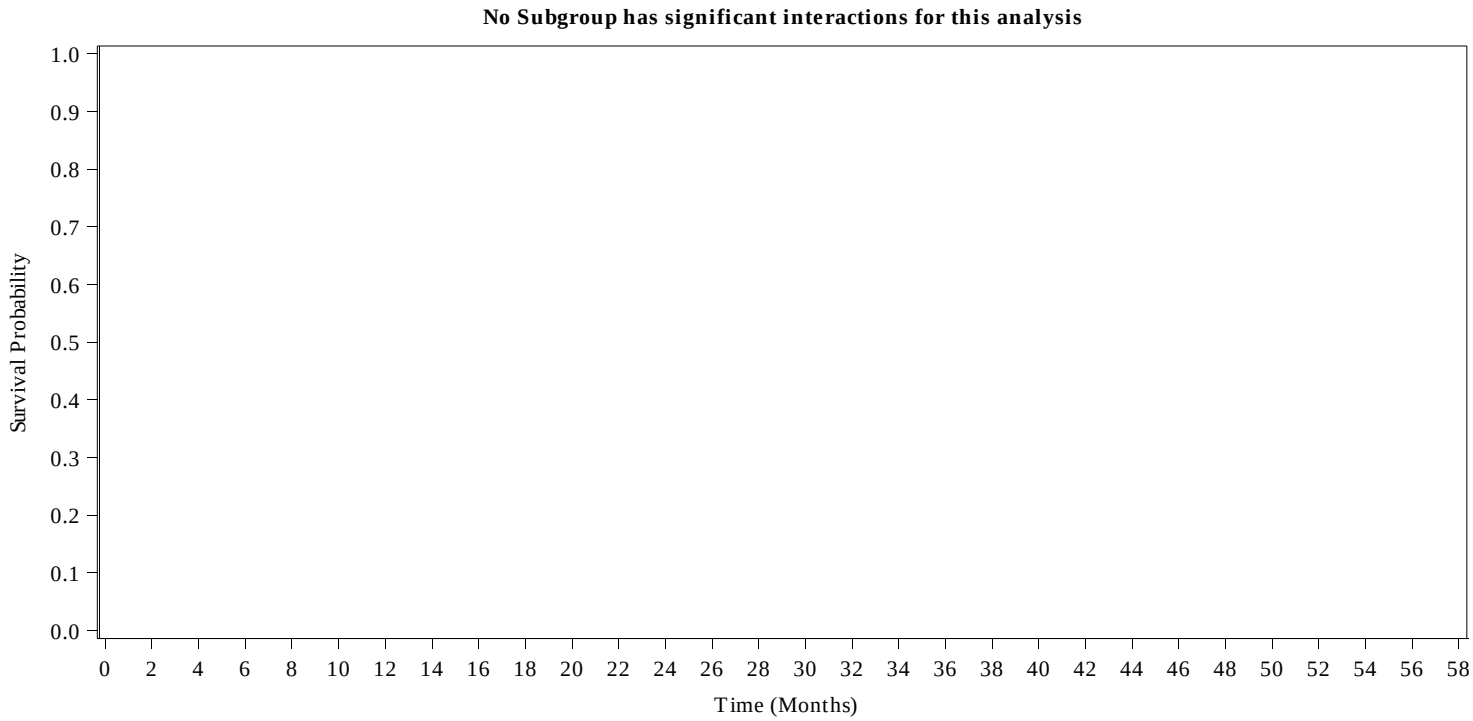
Figure 14.2.4.1.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-subgrp.sas 14NOV2024 06:03 f-14-2-4-1-s-km-subgrp-pfs-pop1-cl.rtf

Table 14.2.4.1:
Objective Response
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	11	8				
%	84.6	47.1	5.133 (0.675, 39.019)	1.477 (0.952, 2.292)	27.000 (-5.071, 59.071)	0.1117
Best Overall Response (BOR), n (%)						
Complete Response (CR)	2 (15.4)	1 (5.9)				
Partial Response (PR)	9 (69.2)	7 (41.2)				
Stable Disease (SD) [e]	2 (15.4)	5 (29.4)				
Progressive Disease (PD)	0 (0.0)	4 (23.5)				
Not Evaluable (NE) [c]	0 (0.0)	0 (0.0)				
Not Assessable [d]	0 (0.0)	0 (0.0)				
Disease Control Rate (DCR), n	13	13				
%	100.0	76.5	NE (NE, NE)	1.292 (0.981, 1.702)	22.600 (0.459, 44.741)	0.0975

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE, not estimable.

Percentages were based on N. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

[c] Not evaluable is based on RECIST v1.1.

[d] Patients with no post-baseline tumor assessment, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.

[e] SD includes SD and non-CR/non-PD.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Age								
Age < 65	9	7 (77.8)	8	3 (37.5)	5.833 (0.696, 48.873)	2.074 (0.794, 5.419)	40.278 (-2.887, 83.442)	0.1023
Age >= 65	4	4 (100.0)	9	5 (55.6)	NE (NE, NE)	1.800 (1.003, 3.229)	44.444 (11.981, 76.908)	0.1237
Interaction								0.4682
Sex								
Male	9	8 (88.9)	11	5 (45.5)	9.600 (0.876, 105.166)	1.956 (0.983, 3.888)	43.434 (7.554, 79.315)	0.0483
Female	4	3 (75.0)	6	3 (50.0)	3.000 (0.188, 47.963)	1.500 (0.563, 3.997)	25.000 (-33.321, 83.321)	0.4533
Interaction								0.5300

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.
ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).
[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.
[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Subgroup	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	Tislelizumab + Chemotherapy (N = 13) Responders n (%)	Placebo + Chemotherapy (N = 17) Total No. of Patients	Placebo + Chemotherapy (N = 17) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
ECOG Performance Score								
0	7	5 (71.4)	10	5 (50.0)	2.500 (0.320, 19.529)	1.429 (0.657, 3.107)	21.429 (-24.182, 67.039)	0.3914
1	6	6 (100.0)	7	3 (42.9)	NE (NE, NE)	2.333 (0.992, 5.489)	57.143 (20.483, 93.803)	0.0325
Interaction								0.1711
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	7	2 (28.6)	7.500 (0.458, 122.696)	2.625 (0.715, 9.640)	46.429 (-7.614, 100.000)	0.1561
No	9	8 (88.9)	10	6 (60.0)	5.333 (0.468, 60.797)	1.481 (0.849, 2.584)	28.889 (-7.765, 65.543)	0.1646
Interaction								0.8566

Source: ADSL, ADTTE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, total number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was calculated using the unstratified Chi-square test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	66.7	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
Cycle 46		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 48		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 50		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 52		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 56		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 58		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 60		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 64		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 66		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 68		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 70		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 72		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
End of Treatment		
Patients in study at visit, n	12	16
Patients complete questionnaire, n	11	16
Completion rate (%) [a]	84.6	94.1
Adjusted completion rate (%) [b]	91.7	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	11
Completion rate (%) [a]	84.6	64.7
Adjusted completion rate (%) [b]	100.0	91.7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	7	9
Completion rate (%) [a]	53.8	52.9
Adjusted completion rate (%) [b]	77.8	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	66.7	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	0	1
Completion rate (%) [a]	0.0	5.9
Adjusted completion rate (%) [b]	0.0	100.0
Cycle 46		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 48		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 50		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 52		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 56		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 58		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 64		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 66		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 68		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 70		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 72		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
End of Treatment		
Patients in study at visit, n	12	16
Patients complete questionnaire, n	11	16
Completion rate (%) [a]	84.6	94.1
Adjusted completion rate (%) [b]	91.7	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Baseline		
Patients in study at visit, n	13	17
Patients complete questionnaire, n	12	17
Completion rate (%) [a]	92.3	100.0
Adjusted completion rate (%) [b]	92.3	100.0
Cycle 2		
Patients in study at visit, n	11	16
Patients complete questionnaire, n	11	15
Completion rate (%) [a]	84.6	88.2
Adjusted completion rate (%) [b]	100.0	93.8
Cycle 3		
Patients in study at visit, n	11	12
Patients complete questionnaire, n	11	12
Completion rate (%) [a]	84.6	70.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 4		
Patients in study at visit, n	10	12
Patients complete questionnaire, n	10	12
Completion rate (%) [a]	76.9	70.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 5		
Patients in study at visit, n	9	11
Patients complete questionnaire, n	9	11
Completion rate (%) [a]	69.2	64.7
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 6		
Patients in study at visit, n	9	9
Patients complete questionnaire, n	8	9
Completion rate (%) [a]	61.5	52.9
Adjusted completion rate (%) [b]	88.9	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 8		
Patients in study at visit, n	9	7
Patients complete questionnaire, n	8	7
Completion rate (%) [a]	61.5	41.2
Adjusted completion rate (%) [b]	88.9	100.0
Cycle 10		
Patients in study at visit, n	5	6
Patients complete questionnaire, n	5	6
Completion rate (%) [a]	38.5	35.3
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 12		
Patients in study at visit, n	4	5
Patients complete questionnaire, n	4	5
Completion rate (%) [a]	30.8	29.4
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 14		
Patients in study at visit, n	4	4
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	75.0
Cycle 16		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	66.7
Cycle 18		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 20		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 22		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 24		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	3	3
Completion rate (%) [a]	23.1	17.6
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 26		
Patients in study at visit, n	4	3
Patients complete questionnaire, n	4	3
Completion rate (%) [a]	30.8	17.6
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 28		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	4	2
Completion rate (%) [a]	30.8	11.8
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 30		
Patients in study at visit, n	4	2
Patients complete questionnaire, n	3	2
Completion rate (%) [a]	23.1	11.8
Adjusted completion rate (%) [b]	75.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 32		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 34		
Patients in study at visit, n	4	1
Patients complete questionnaire, n	4	1
Completion rate (%) [a]	30.8	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 36		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	3	1
Completion rate (%) [a]	23.1	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 38		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	66.7	100.0
Cycle 40		
Patients in study at visit, n	3	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	33.3	100.0
Cycle 42		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	2	1
Completion rate (%) [a]	15.4	5.9
Adjusted completion rate (%) [b]	100.0	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 44		
Patients in study at visit, n	2	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	50.0	100.0
Cycle 46		
Patients in study at visit, n	1	1
Patients complete questionnaire, n	1	1
Completion rate (%) [a]	7.7	5.9
Adjusted completion rate (%) [b]	100.0	100.0
Cycle 48		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 50		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 52		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 54		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 56		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 58		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 60		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 62		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 64		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 66		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Cycle 68		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 70		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0
Cycle 72		
Patients in study at visit, n	1	0
Patients complete questionnaire, n	1	0
Completion rate (%) [a]	7.7	0.0
Adjusted completion rate (%) [b]	100.0	0.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Questionnaire: EQ-5D VAS

Visit	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
End of Treatment		
Patients in study at visit, n	12	16
Patients complete questionnaire, n	11	16
Completion rate (%) [a]	84.6	94.1
Adjusted completion rate (%) [b]	91.7	100.0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients on study treatment at relevant visits in relevant treatment arm.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-comp.sas 14NOV2024 06:32 t-14-2-6-1-1-qs-comp-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	63.2 (29.83)		57.8 (25.08)	
	Median	83.3		50.0	
	Q1, Q3	37.5, 83.3		50.0, 75.0	
	Min, Max	0, 83		8, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	74.2 (16.87)	10.8 (26.95)	62.2 (20.14)	5.6 (20.33)
	Median	83.3	4.2	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 8.3	50.0, 83.3	-8.3, 25.0
	Min, Max	33, 92	-17, 67	25, 83	-42, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	75.8 (12.08)	12.5 (28.40)	62.5 (26.94)	5.6 (20.21)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 83.3	0.0, 33.3	58.3, 75.0	0.0, 16.7
	Min, Max	58, 92	-25, 67	8, 100	-33, 50

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	77.8 (13.82)	16.7 (23.57)	60.4 (27.55)	3.5 (26.93)
	Median	83.3	8.3	75.0	4.2
	Q1, Q3	66.7, 83.3	0.0, 41.7	41.7, 79.2	-16.7, 20.8
	Min, Max	50, 92	-8, 50	8, 83	-42, 42
Cycle 5	n	8	8	11	11
	Mean (SD)	78.1 (17.78)	12.5 (19.42)	64.4 (26.38)	3.0 (28.69)
	Median	83.3	4.2	66.7	16.7
	Q1, Q3	70.8, 87.5	0.0, 29.2	41.7, 83.3	-25.0, 16.7
	Min, Max	42, 100	-8, 42	17, 100	-42, 42
Cycle 6	n	7	7	9	9
	Mean (SD)	81.0 (11.50)	6.0 (15.75)	71.3 (24.69)	7.4 (28.09)
	Median	83.3	0.0	83.3	0.0
	Q1, Q3	66.7, 83.3	0.0, 16.7	66.7, 83.3	-8.3, 33.3
	Min, Max	67, 100	-17, 33	17, 100	-33, 50

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	81.0 (15.00)	17.9 (22.79)	85.7 (11.50)	17.9 (26.97)
	Median	83.3	8.3	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 100.0	0.0, 41.7
	Min, Max	50, 100	0, 50	67, 100	-8, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (27.22)	16.7 (23.57)	75.0 (29.34)	6.9 (36.29)
	Median	66.7	25.0	83.3	4.2
	Q1, Q3	50.0, 83.3	0.0, 33.3	83.3, 83.3	-8.3, 41.7
	Min, Max	33, 100	-17, 33	17, 100	-50, 50
Cycle 12	n	3	3	5	5
	Mean (SD)	75.0 (14.43)	36.1 (42.76)	70.0 (21.73)	8.3 (31.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	58.3, 83.3	0.0, 83.3	66.7, 83.3	-8.3, 25.0
	Min, Max	58, 83	0, 83	33, 83	-33, 50

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	80.6 (12.73)	41.7 (30.05)	75.0 (8.33)	16.7 (22.05)
	Median	83.3	50.0	75.0	8.3
	Q1, Q3	66.7, 91.7	8.3, 66.7	66.7, 83.3	0.0, 41.7
	Min, Max	67, 92	8, 67	67, 83	0, 42
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	38.9 (25.46)	66.7 (23.57)	-12.5 (5.89)
	Median	66.7	33.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	16.7, 66.7	50.0, 83.3	-16.7, -8.3
	Min, Max	67, 100	17, 67	50, 83	-17, -8
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (34.69)	16.7 (16.67)	72.2 (19.25)	-5.6 (12.73)
	Median	66.7	16.7	83.3	-8.3
	Q1, Q3	16.7, 83.3	0.0, 33.3	50.0, 83.3	-16.7, 8.3
	Min, Max	17, 83	0, 33	50, 83	-17, 8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	72.2 (19.25)	33.3 (28.87)	80.6 (4.81)	2.8 (9.62)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 83.3	0.0, 50.0	75.0, 83.3	-8.3, 8.3
	Min, Max	50, 83	0, 50	75, 83	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (25.46)	38.9 (19.25)	77.8 (9.62)	0.0 (22.05)
	Median	83.3	50.0	83.3	8.3
	Q1, Q3	50.0, 100.0	16.7, 50.0	66.7, 83.3	-25.0, 16.7
	Min, Max	50, 100	17, 50	67, 83	-25, 17
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	83.3 (0.00)	5.6 (12.73)
	Median	83.3	25.0	83.3	8.3
	Q1, Q3	83.3, 83.3	0.0, 50.0	83.3, 83.3	-8.3, 16.7
	Min, Max	83, 83	0, 50	83, 83	-8, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (0.00)	25.0 (35.36)	77.8 (9.62)	0.0 (8.33)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	83.3, 83.3	0.0, 50.0	66.7, 83.3	-8.3, 8.3
	Min, Max	83, 83	0, 50	67, 83	-8, 8
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	25.0 (11.79)	83.3 (0.00)	4.2 (17.68)
	Median	83.3	25.0	83.3	4.2
	Q1, Q3	66.7, 100.0	16.7, 33.3	83.3, 83.3	-8.3, 16.7
	Min, Max	67, 100	17, 33	83, 83	-8, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	66.7 (23.57)	50.0 (0.00)	83.3 (0.00)	4.2 (17.68)
	Median	66.7	50.0	83.3	4.2
	Q1, Q3	50.0, 83.3	50.0, 50.0	83.3, 83.3	-8.3, 16.7
	Min, Max	50, 83	50, 50	83, 83	-8, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	61.1 (25.46)	22.2 (19.25)	83.3 (NE)	-8.3 (NE)
	Median	66.7	33.3	83.3	-8.3
	Q1, Q3	33.3, 83.3	0.0, 33.3	83.3, 83.3	-8.3, -8.3
	Min, Max	33, 83	0, 33	83, 83	-8, -8
Cycle 34	n	3	3	1	1
	Mean (SD)	66.7 (33.33)	27.8 (9.62)	75.0 (NE)	-16.7 (NE)
	Median	66.7	33.3	75.0	-16.7
	Q1, Q3	33.3, 100.0	16.7, 33.3	75.0, 75.0	-16.7, -16.7
	Min, Max	33, 100	17, 33	75, 75	-17, -17
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	16.7 (NE)	83.3 (NE)	-8.3 (NE)
	Median	100.0	16.7	83.3	-8.3
	Q1, Q3	100.0, 100.0	16.7, 16.7	83.3, 83.3	-8.3, -8.3
	Min, Max	100, 100	17, 17	83, 83	-8, -8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			91.7 (NE)	0.0 (NE)
	Median			91.7	0.0
	Q1, Q3			91.7, 91.7	0.0, 0.0
	Min, Max			92, 92	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	1	1	1	1
	Mean (SD)	50.0 (NE)	50.0 (NE)	75.0 (NE)	-16.7 (NE)
	Median	50.0	50.0	75.0	-16.7
	Q1, Q3	50.0, 50.0	50.0, 50.0	75.0, 75.0	-16.7, -16.7
	Min, Max	50, 50	50, 50	75, 75	-17, -17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 46	n	1	1	1	1
	Mean (SD)	50.0 (NE)	50.0 (NE)	83.3 (NE)	-8.3 (NE)
	Median	50.0	50.0	83.3	-8.3
	Q1, Q3	50.0, 50.0	50.0, 50.0	83.3, 83.3	-8.3, -8.3
	Min, Max	50, 50	50, 50	83, 83	-8, -8
Cycle 48	n	1	1	0	0
	Mean (SD)	50.0 (NE)	50.0 (NE)		
	Median	50.0	50.0		
	Q1, Q3	50.0, 50.0	50.0, 50.0		
	Min, Max	50, 50	50, 50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 52	n	1	1	0	0
	Mean (SD)	50.0 (NE)	50.0 (NE)		
	Median	50.0	50.0		
	Q1, Q3	50.0, 50.0	50.0, 50.0		
	Min, Max	50, 50	50, 50		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		
Cycle 64	n	1	1	0	0
	Mean (SD)	25.0 (NE)	25.0 (NE)		
	Median	25.0	25.0		
	Q1, Q3	25.0, 25.0	25.0, 25.0		
	Min, Max	25, 25	25, 25		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	50.0 (NE)	50.0 (NE)		
	Median	50.0	50.0		
	Q1, Q3	50.0, 50.0	50.0, 50.0		
	Min, Max	50, 50	50, 50		
Cycle 68	n	1	1	0	0
	Mean (SD)	41.7 (NE)	41.7 (NE)		
	Median	41.7	41.7		
	Q1, Q3	41.7, 41.7	41.7, 41.7		
	Min, Max	42, 42	42, 42		
Cycle 70	n	1	1	0	0
	Mean (SD)	50.0 (NE)	50.0 (NE)		
	Median	50.0	50.0		
	Q1, Q3	50.0, 50.0	50.0, 50.0		
	Min, Max	50, 50	50, 50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	41.7 (NE)	41.7 (NE)		
	Median	41.7	41.7		
	Q1, Q3	41.7, 41.7	41.7, 41.7		
	Min, Max	42, 42	42, 42		
End of Treatment	n	10	10	16	16
	Mean (SD)	68.3 (15.11)	5.0 (27.27)	59.4 (25.98)	1.0 (22.33)
	Median	66.7	-4.2	66.7	0.0
	Q1, Q3	66.7, 83.3	-16.7, 33.3	41.7, 75.0	-8.3, 8.3
	Min, Max	33, 83	-25, 58	0, 100	-50, 42

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Global health status / QoL

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	56.9 (22.14)	-6.3 (13.35)	44.1 (23.89)	-13.7 (21.84)
	Median	66.7	-8.3	50.0	-8.3
	Q1, Q3	45.8, 66.7	-16.7, 0.0	33.3, 66.7	-25.0, 0.0
	Min, Max	17, 83	-25, 17	0, 75	-50, 25

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.7 (21.84)		87.1 (14.23)	
	Median	100.0		86.7	
	Q1, Q3	70.0, 100.0		86.7, 93.3	
	Min, Max	47, 100		47, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	87.3 (18.18)	2.0 (11.78)	77.3 (22.65)	-8.9 (13.25)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 93.3	-13.3, 0.0
	Min, Max	53, 100	-20, 27	20, 100	-40, 13
Cycle 3	n	10	10	12	12
	Mean (SD)	88.0 (19.58)	2.7 (10.04)	73.9 (21.36)	-14.4 (11.66)
	Median	100.0	0.0	80.0	-10.0
	Q1, Q3	80.0, 100.0	0.0, 0.0	66.7, 86.7	-26.7, -6.7
	Min, Max	47, 100	-7, 27	20, 100	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.9 (23.67)	2.2 (14.53)	75.6 (23.33)	-12.8 (12.86)
	Median	100.0	0.0	80.0	-13.3
	Q1, Q3	86.7, 100.0	0.0, 0.0	66.7, 93.3	-23.3, 0.0
	Min, Max	33, 100	-20, 33	13, 100	-33, 7
Cycle 5	n	8	8	11	11
	Mean (SD)	86.7 (24.43)	-0.8 (10.95)	82.4 (15.57)	-9.7 (13.78)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	80.0, 100.0	-3.3, 0.0	66.7, 100.0	-26.7, 0.0
	Min, Max	33, 100	-20, 20	60, 100	-27, 13
Cycle 6	n	7	7	9	9
	Mean (SD)	94.3 (15.12)	1.9 (5.04)	83.7 (12.96)	-8.9 (11.55)
	Median	100.0	0.0	86.7	-6.7
	Q1, Q3	100.0, 100.0	0.0, 0.0	80.0, 93.3	-13.3, 0.0
	Min, Max	60, 100	0, 13	60, 100	-27, 7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	82.9 (27.72)	-2.9 (8.48)	89.5 (12.68)	-4.8 (10.69)
	Median	100.0	0.0	93.3	0.0
	Q1, Q3	53.3, 100.0	-6.7, 0.0	80.0, 100.0	-6.7, 0.0
	Min, Max	33, 100	-20, 7	67, 100	-27, 7
Cycle 10	n	4	4	6	6
	Mean (SD)	66.7 (35.69)	-8.3 (8.39)	86.7 (26.67)	-6.7 (26.67)
	Median	70.0	-6.7	100.0	0.0
	Q1, Q3	36.7, 96.7	-13.3, -3.3	86.7, 100.0	0.0, 6.7
	Min, Max	27, 100	-20, 0	33, 100	-60, 13
Cycle 12	n	3	3	5	5
	Mean (SD)	64.4 (30.79)	-2.2 (3.85)	85.3 (15.20)	-6.7 (13.33)
	Median	46.7	0.0	86.7	0.0
	Q1, Q3	46.7, 100.0	-6.7, 0.0	73.3, 100.0	-13.3, 0.0
	Min, Max	47, 100	-7, 0	67, 100	-27, 7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	91.1 (7.70)	24.4 (21.43)	88.9 (13.88)	-4.4 (13.88)
	Median	86.7	33.3	93.3	0.0
	Q1, Q3	86.7, 100.0	0.0, 40.0	73.3, 100.0	-20.0, 6.7
	Min, Max	87, 100	0, 40	73, 100	-20, 7
Cycle 16	n	3	3	2	2
	Mean (SD)	75.6 (23.41)	8.9 (15.40)	83.3 (23.57)	-10.0 (23.57)
	Median	73.3	0.0	83.3	-10.0
	Q1, Q3	53.3, 100.0	0.0, 26.7	66.7, 100.0	-26.7, 6.7
	Min, Max	53, 100	0, 27	67, 100	-27, 7
Cycle 18	n	3	3	3	3
	Mean (SD)	73.3 (24.04)	6.7 (11.55)	75.6 (10.18)	-15.6 (13.88)
	Median	66.7	0.0	73.3	-20.0
	Q1, Q3	53.3, 100.0	0.0, 20.0	66.7, 86.7	-26.7, 0.0
	Min, Max	53, 100	0, 20	67, 87	-27, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	77.8 (23.41)	11.1 (19.25)	82.2 (13.88)	-8.9 (15.40)
	Median	80.0	0.0	86.7	0.0
	Q1, Q3	53.3, 100.0	0.0, 33.3	66.7, 93.3	-26.7, 0.0
	Min, Max	53, 100	0, 33	67, 93	-27, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	73.3 (30.55)	6.7 (24.04)	93.3 (6.67)	2.2 (3.85)
	Median	80.0	0.0	93.3	0.0
	Q1, Q3	40.0, 100.0	-13.3, 33.3	86.7, 100.0	0.0, 6.7
	Min, Max	40, 100	-13, 33	87, 100	0, 7
Cycle 24	n	2	2	3	3
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	82.2 (10.18)	-8.9 (13.88)
	Median	90.0	16.7	80.0	-13.3
	Q1, Q3	80.0, 100.0	0.0, 33.3	73.3, 93.3	-20.0, 6.7
	Min, Max	80, 100	0, 33	73, 93	-20, 7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	86.7 (18.86)	13.3 (18.86)	86.7 (6.67)	-4.4 (10.18)
	Median	86.7	13.3	86.7	-6.7
	Q1, Q3	73.3, 100.0	0.0, 26.7	80.0, 93.3	-13.3, 6.7
	Min, Max	73, 100	0, 27	80, 93	-13, 7
Cycle 28	n	2	2	2	2
	Mean (SD)	90.0 (14.14)	16.7 (23.57)	90.0 (14.14)	-3.3 (14.14)
	Median	90.0	16.7	90.0	-3.3
	Q1, Q3	80.0, 100.0	0.0, 33.3	80.0, 100.0	-13.3, 6.7
	Min, Max	80, 100	0, 33	80, 100	-13, 7
Cycle 30	n	2	2	2	2
	Mean (SD)	76.7 (14.14)	26.7 (18.86)	83.3 (23.57)	-10.0 (23.57)
	Median	76.7	26.7	83.3	-10.0
	Q1, Q3	66.7, 86.7	13.3, 40.0	66.7, 100.0	-26.7, 6.7
	Min, Max	67, 87	13, 40	67, 100	-27, 7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	80.0 (24.04)	13.3 (23.09)	93.3 (NE)	0.0 (NE)
	Median	86.7	0.0	93.3	0.0
	Q1, Q3	53.3, 100.0	0.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	53, 100	0, 40	93, 93	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	73.3 (35.28)	6.7 (30.55)	93.3 (NE)	0.0 (NE)
	Median	86.7	0.0	93.3	0.0
	Q1, Q3	33.3, 100.0	-20.0, 40.0	93.3, 93.3	0.0, 0.0
	Min, Max	33, 100	-20, 40	93, 93	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	100.0 (NE)	6.7 (NE)
	Median	100.0	0.0	100.0	6.7
	Q1, Q3	100.0, 100.0	0.0, 0.0	100.0, 100.0	6.7, 6.7
	Min, Max	100, 100	0, 0	100, 100	7, 7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	60.0 (NE)	6.7 (NE)	86.7 (NE)	-6.7 (NE)
	Median	60.0	6.7	86.7	-6.7
	Q1, Q3	60.0, 60.0	6.7, 6.7	86.7, 86.7	-6.7, -6.7
	Min, Max	60, 60	7, 7	87, 87	-7, -7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			93.3 (NE)	0.0 (NE)
	Median			93.3	0.0
	Q1, Q3			93.3, 93.3	0.0, 0.0
	Min, Max			93, 93	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	13.3 (NE)	93.3 (NE)	0.0 (NE)
	Median	66.7	13.3	93.3	0.0
	Q1, Q3	66.7, 66.7	13.3, 13.3	93.3, 93.3	0.0, 0.0
	Min, Max	67, 67	13, 13	93, 93	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	53.3 (NE)	0.0 (NE)		
	Median	53.3	0.0		
	Q1, Q3	53.3, 53.3	0.0, 0.0		
	Min, Max	53, 53	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	60.0 (NE)	6.7 (NE)		
	Median	60.0	6.7		
	Q1, Q3	60.0, 60.0	6.7, 6.7		
	Min, Max	60, 60	7, 7		
Cycle 52	n	1	1	0	0
	Mean (SD)	40.0 (NE)	-13.3 (NE)		
	Median	40.0	-13.3		
	Q1, Q3	40.0, 40.0	-13.3, -13.3		
	Min, Max	40, 40	-13, -13		
Cycle 56	n	1	1	0	0
	Mean (SD)	60.0 (NE)	6.7 (NE)		
	Median	60.0	6.7		
	Q1, Q3	60.0, 60.0	6.7, 6.7		
	Min, Max	60, 60	7, 7		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	46.7 (NE)	-6.7 (NE)		
	Median	46.7	-6.7		
	Q1, Q3	46.7, 46.7	-6.7, -6.7		
	Min, Max	47, 47	-7, -7		
Cycle 60	n	1	1	0	0
	Mean (SD)	46.7 (NE)	-6.7 (NE)		
	Median	46.7	-6.7		
	Q1, Q3	46.7, 46.7	-6.7, -6.7		
	Min, Max	47, 47	-7, -7		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-20.0 (NE)		
	Median	33.3	-20.0		
	Q1, Q3	33.3, 33.3	-20.0, -20.0		
	Min, Max	33, 33	-20, -20		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	66.7 (NE)	13.3 (NE)		
	Median	66.7	13.3		
	Q1, Q3	66.7, 66.7	13.3, 13.3		
	Min, Max	67, 67	13, 13		
Cycle 68	n	1	1	0	0
	Mean (SD)	53.3 (NE)	0.0 (NE)		
	Median	53.3	0.0		
	Q1, Q3	53.3, 53.3	0.0, 0.0		
	Min, Max	53, 53	0, 0		
Cycle 70	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-20.0 (NE)		
	Median	33.3	-20.0		
	Q1, Q3	33.3, 33.3	-20.0, -20.0		
	Min, Max	33, 33	-20, -20		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-20.0 (NE)		
	Median	33.3	-20.0		
	Q1, Q3	33.3, 33.3	-20.0, -20.0		
	Min, Max	33, 33	-20, -20		
End of Treatment	n	10	10	16	16
	Mean (SD)	85.3 (16.27)	0.0 (19.37)	72.1 (25.67)	-15.0 (16.95)
	Median	86.7	-3.3	83.3	-6.7
	Q1, Q3	80.0, 100.0	-13.3, 0.0	60.0, 86.7	-26.7, 0.0
	Min, Max	47, 100	-27, 33	7, 100	-53, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Physical functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	76.7 (25.66)	-10.0 (9.64)	60.4 (23.39)	-26.7 (15.63)
	Median	83.3	-6.7	66.7	-26.7
	Q1, Q3	63.3, 96.7	-20.0, 0.0	46.7, 80.0	-33.3, -13.3
	Min, Max	27, 100	-27, 0	7, 87	-60, -7

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	86.1 (21.12)		79.4 (26.70)	
	Median	100.0		100.0	
	Q1, Q3	75.0, 100.0		66.7, 100.0	
	Min, Max	33, 100		17, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	88.3 (17.66)	3.3 (7.03)	71.1 (31.16)	-8.9 (18.76)
	Median	100.0	0.0	83.3	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 17	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	88.3 (22.29)	3.3 (10.54)	70.8 (29.41)	-9.7 (18.06)
	Median	100.0	0.0	75.0	-16.7
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 91.7	-16.7, 0.0
	Min, Max	33, 100	0, 33	0, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	83.3 (33.33)	-1.9 (26.93)	70.8 (32.66)	-9.7 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	85.4 (27.37)	-2.1 (5.89)	78.8 (21.20)	-7.6 (18.80)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	90.5 (25.20)	0.0 (0.00)	79.6 (18.22)	-7.4 (16.90)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	0, 0	50, 100	-33, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	83.3 (28.87)	-2.4 (6.30)	95.2 (12.60)	0.0 (19.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	50.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-17, 0	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	58.3 (50.00)	-16.7 (19.25)	88.9 (27.22)	-5.6 (32.77)
	Median	66.7	-16.7	100.0	0.0
	Q1, Q3	16.7, 100.0	-33.3, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	55.6 (50.92)	-11.1 (19.25)	73.3 (30.28)	-20.0 (21.73)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	0.0, 100.0	-33.3, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 0	33, 100	-50, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	16.7 (16.67)	83.3 (28.87)	-16.7 (28.87)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	50.0, 100.0	-50.0, 0.0
	Min, Max	67, 100	0, 33	50, 100	-50, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	66.7 (33.33)	0.0 (0.00)	83.3 (23.57)	-16.7 (23.57)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	33.3, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	0, 0	67, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	55.6 (38.49)	-11.1 (19.25)	88.9 (19.25)	-11.1 (19.25)
	Median	33.3	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	55.6 (50.92)	-11.1 (50.92)	88.9 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-67, 33	67, 100	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	72.2 (25.46)	5.6 (25.46)	83.3 (16.67)	-16.7 (16.67)
	Median	66.7	0.0	83.3	-16.7
	Q1, Q3	50.0, 100.0	-16.7, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	50, 100	-17, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	83.3 (16.67)	-16.7 (16.67)
	Median	83.3	16.7	83.3	-16.7
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	88.9 (19.25)	-11.1 (19.25)
	Median	83.3	16.7	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	16.7 (23.57)	83.3 (23.57)	-16.7 (23.57)
	Median	83.3	16.7	83.3	-16.7
	Q1, Q3	66.7, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	66.7 (0.00)	16.7 (23.57)	83.3 (23.57)	-16.7 (23.57)
	Median	66.7	16.7	83.3	-16.7
	Q1, Q3	66.7, 66.7	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 67	0, 33	67, 100	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	55.6 (50.92)	-11.1 (50.92)	100.0 (NE)	0.0 (NE)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	0, 100	-67, 33	100, 100	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	66.7 (33.33)	0.0 (33.33)	100.0 (NE)	0.0 (NE)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-33.3, 33.3	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-33, 33	100, 100	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	100.0 (NE)	0.0 (NE)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	100, 100	0, 0	100, 100	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			83.3 (NE)	-16.7 (NE)
	Median			83.3	-16.7
	Q1, Q3			83.3, 83.3	-16.7, -16.7
	Min, Max			83, 83	-17, -17
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-33.3 (NE)	66.7 (NE)	-33.3 (NE)
	Median	33.3	-33.3	66.7	-33.3
	Q1, Q3	33.3, 33.3	-33.3, -33.3	66.7, 66.7	-33.3, -33.3
	Min, Max	33, 33	-33, -33	67, 67	-33, -33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-33.3 (NE)	66.7 (NE)	-33.3 (NE)
	Median	33.3	-33.3	66.7	-33.3
	Q1, Q3	33.3, 33.3	-33.3, -33.3	66.7, 66.7	-33.3, -33.3
	Min, Max	33, 33	-33, -33	67, 67	-33, -33
Cycle 48	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-16.7 (NE)		
	Median	50.0	-16.7		
	Q1, Q3	50.0, 50.0	-16.7, -16.7		
	Min, Max	50, 50	-17, -17		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-16.7 (NE)		
	Median	50.0	-16.7		
	Q1, Q3	50.0, 50.0	-16.7, -16.7		
	Min, Max	50, 50	-17, -17		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 56	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-16.7 (NE)		
	Median	50.0	-16.7		
	Q1, Q3	50.0, 50.0	-16.7, -16.7		
	Min, Max	50, 50	-17, -17		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-50.0 (NE)		
	Median	16.7	-50.0		
	Q1, Q3	16.7, 16.7	-50.0, -50.0		
	Min, Max	17, 17	-50, -50		
Cycle 60	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-50.0 (NE)		
	Median	16.7	-50.0		
	Q1, Q3	16.7, 16.7	-50.0, -50.0		
	Min, Max	17, 17	-50, -50		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-50.0 (NE)		
	Median	16.7	-50.0		
	Q1, Q3	16.7, 16.7	-50.0, -50.0		
	Min, Max	17, 17	-50, -50		
Cycle 68	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 70	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-50.0 (NE)		
	Median	16.7	-50.0		
	Q1, Q3	16.7, 16.7	-50.0, -50.0		
	Min, Max	17, 17	-50, -50		
End of Treatment	n	10	10	16	16
	Mean (SD)	78.3 (31.48)	-6.7 (29.61)	69.8 (29.32)	-10.4 (15.96)
	Median	91.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	58.3, 100.0	-16.7, 0.0
	Min, Max	0, 100	-67, 33	0, 100	-50, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Role functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	69.4 (36.81)	-16.7 (20.10)	53.9 (29.77)	-25.5 (18.74)
	Median	75.0	-16.7	66.7	-33.3
	Q1, Q3	58.3, 100.0	-25.0, 0.0	33.3, 66.7	-33.3, -16.7
	Min, Max	0, 100	-67, 0	0, 100	-67, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	72.9 (27.55)		75.5 (20.08)	
	Median	83.3		75.0	
	Q1, Q3	62.5, 87.5		66.7, 91.7	
	Min, Max	8, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	90.8 (9.98)	15.8 (19.42)	73.9 (19.89)	-1.1 (22.90)
	Median	91.7	8.3	75.0	0.0
	Q1, Q3	83.3, 100.0	8.3, 16.7	66.7, 83.3	-16.7, 0.0
	Min, Max	75, 100	0, 67	17, 100	-25, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	94.2 (11.15)	19.2 (23.59)	75.0 (12.31)	0.7 (17.21)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	91.7, 100.0	8.3, 16.7	66.7, 83.3	-8.3, 8.3
	Min, Max	67, 100	0, 83	50, 100	-25, 42

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	87.0 (20.46)	13.0 (17.73)	75.0 (22.47)	0.7 (16.84)
	Median	100.0	16.7	79.2	0.0
	Q1, Q3	83.3, 100.0	0.0, 16.7	62.5, 91.7	-8.3, 8.3
	Min, Max	42, 100	-17, 42	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	89.6 (15.27)	14.6 (15.91)	75.8 (19.17)	0.8 (22.19)
	Median	95.8	12.5	83.3	0.0
	Q1, Q3	83.3, 100.0	4.2, 16.7	66.7, 83.3	-8.3, 16.7
	Min, Max	58, 100	0, 50	33, 100	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	10.7 (7.93)	77.8 (18.63)	-2.8 (18.16)
	Median	100.0	16.7	75.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 16.7	66.7, 91.7	-16.7, 8.3
	Min, Max	67, 100	0, 17	42, 100	-25, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	89.3 (14.20)	15.5 (20.65)	86.9 (10.60)	3.6 (10.60)
	Median	100.0	16.7	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 16.7	83.3, 91.7	0.0, 8.3
	Min, Max	67, 100	0, 58	67, 100	-8, 25
Cycle 10	n	4	4	6	6
	Mean (SD)	79.2 (14.43)	16.7 (28.87)	86.1 (26.70)	2.8 (21.52)
	Median	79.2	8.3	100.0	4.2
	Q1, Q3	66.7, 91.7	0.0, 33.3	83.3, 100.0	0.0, 8.3
	Min, Max	67, 92	-8, 58	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	94.4 (9.62)	38.9 (47.39)	81.7 (27.89)	1.7 (23.86)
	Median	100.0	25.0	91.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 91.7	83.3, 100.0	0.0, 8.3
	Min, Max	83, 100	0, 92	33, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	86.1 (12.73)	30.6 (33.68)	80.6 (12.73)	0.0 (16.67)
	Median	83.3	25.0	83.3	0.0
	Q1, Q3	75.0, 100.0	0.0, 66.7	66.7, 91.7	-16.7, 16.7
	Min, Max	75, 100	0, 67	67, 92	-17, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (35.36)	-12.5 (17.68)
	Median	66.7	8.3	66.7	-12.5
	Q1, Q3	66.7, 100.0	0.0, 58.3	41.7, 91.7	-25.0, 0.0
	Min, Max	67, 100	0, 58	42, 92	-25, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	80.6 (17.35)	25.0 (30.05)	83.3 (16.67)	-2.8 (4.81)
	Median	75.0	16.7	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 58.3	66.7, 100.0	-8.3, 0.0
	Min, Max	67, 100	0, 58	67, 100	-8, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	38.9 (37.58)	86.1 (24.06)	0.0 (8.33)
	Median	100.0	41.7	100.0	0.0
	Q1, Q3	83.3, 100.0	0.0, 75.0	58.3, 100.0	-8.3, 8.3
	Min, Max	83, 100	0, 75	58, 100	-8, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	22.2 (31.55)	66.7 (8.33)	-19.4 (24.06)
	Median	66.7	8.3	66.7	-33.3
	Q1, Q3	66.7, 100.0	0.0, 58.3	58.3, 75.0	-33.3, 8.3
	Min, Max	67, 100	0, 58	58, 75	-33, 8
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	4.2 (5.89)	75.0 (0.00)	-11.1 (17.35)
	Median	83.3	4.2	75.0	-16.7
	Q1, Q3	66.7, 100.0	0.0, 8.3	75.0, 75.0	-25.0, 8.3
	Min, Max	67, 100	0, 8	75, 75	-25, 8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	91.7 (11.79)	12.5 (17.68)	80.6 (12.73)	-5.6 (25.46)
	Median	91.7	12.5	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 25.0	66.7, 91.7	-33.3, 16.7
	Min, Max	83, 100	0, 25	67, 92	-33, 17
Cycle 28	n	2	2	2	2
	Mean (SD)	87.5 (17.68)	8.3 (11.79)	75.0 (11.79)	-4.2 (5.89)
	Median	87.5	8.3	75.0	-4.2
	Q1, Q3	75.0, 100.0	0.0, 16.7	66.7, 83.3	-8.3, 0.0
	Min, Max	75, 100	0, 17	67, 83	-8, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	83.3 (11.79)	50.0 (47.14)	70.8 (17.68)	-8.3 (0.00)
	Median	83.3	50.0	70.8	-8.3
	Q1, Q3	75.0, 91.7	16.7, 83.3	58.3, 83.3	-8.3, -8.3
	Min, Max	75, 92	17, 83	58, 83	-8, -8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	80.6 (17.35)	25.0 (36.32)	83.3 (NE)	-8.3 (NE)
	Median	75.0	8.3	83.3	-8.3
	Q1, Q3	66.7, 100.0	0.0, 66.7	83.3, 83.3	-8.3, -8.3
	Min, Max	67, 100	0, 67	83, 83	-8, -8
Cycle 34	n	3	3	1	1
	Mean (SD)	83.3 (28.87)	27.8 (24.06)	66.7 (NE)	-25.0 (NE)
	Median	100.0	41.7	66.7	-25.0
	Q1, Q3	50.0, 100.0	0.0, 41.7	66.7, 66.7	-25.0, -25.0
	Min, Max	50, 100	0, 42	67, 67	-25, -25
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	83.3 (NE)	-8.3 (NE)
	Median	100.0	0.0	83.3	-8.3
	Q1, Q3	100.0, 100.0	0.0, 0.0	83.3, 83.3	-8.3, -8.3
	Min, Max	100, 100	0, 0	83, 83	-8, -8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 40	n	0	0	1	1
	Mean (SD)			75.0 (NE)	-16.7 (NE)
	Median			75.0	-16.7
	Q1, Q3			75.0, 75.0	-16.7, -16.7
	Min, Max			75, 75	-17, -17
Cycle 42	n	1	1	1	1
	Mean (SD)	75.0 (NE)	66.7 (NE)	83.3 (NE)	-8.3 (NE)
	Median	75.0	66.7	83.3	-8.3
	Q1, Q3	75.0, 75.0	66.7, 66.7	83.3, 83.3	-8.3, -8.3
	Min, Max	75, 75	67, 67	83, 83	-8, -8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-25.0 (NE)
	Median			66.7	-25.0
	Q1, Q3			66.7, 66.7	-25.0, -25.0
	Min, Max			67, 67	-25, -25
Cycle 46	n	1	1	1	1
	Mean (SD)	83.3 (NE)	75.0 (NE)	75.0 (NE)	-16.7 (NE)
	Median	83.3	75.0	75.0	-16.7
	Q1, Q3	83.3, 83.3	75.0, 75.0	75.0, 75.0	-16.7, -16.7
	Min, Max	83, 83	75, 75	75, 75	-17, -17
Cycle 48	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	50.0 (NE)	41.7 (NE)		
	Median	50.0	41.7		
	Q1, Q3	50.0, 50.0	41.7, 41.7		
	Min, Max	50, 50	42, 42		
Cycle 60	n	1	1	0	0
	Mean (SD)	58.3 (NE)	50.0 (NE)		
	Median	58.3	50.0		
	Q1, Q3	58.3, 58.3	50.0, 50.0		
	Min, Max	58, 58	50, 50		
Cycle 64	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	50.0 (NE)	41.7 (NE)		
	Median	50.0	41.7		
	Q1, Q3	50.0, 50.0	41.7, 41.7		
	Min, Max	50, 50	42, 42		
Cycle 68	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		
Cycle 70	n	1	1	0	0
	Mean (SD)	66.7 (NE)	58.3 (NE)		
	Median	66.7	58.3		
	Q1, Q3	66.7, 66.7	58.3, 58.3		
	Min, Max	67, 67	58, 58		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	50.0 (NE)	41.7 (NE)		
	Median	50.0	41.7		
	Q1, Q3	50.0, 50.0	41.7, 41.7		
	Min, Max	50, 50	42, 42		
End of Treatment	n	10	10	16	16
	Mean (SD)	85.0 (17.03)	10.8 (27.23)	70.8 (21.73)	-7.3 (17.45)
	Median	91.7	8.3	75.0	-4.2
	Q1, Q3	66.7, 100.0	0.0, 33.3	58.3, 87.5	-25.0, 8.3
	Min, Max	58, 100	-42, 50	25, 100	-33, 25

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Emotional functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	70.8 (23.44)	-2.1 (18.84)	58.8 (19.43)	-16.7 (13.82)
	Median	75.0	0.0	66.7	-16.7
	Q1, Q3	62.5, 87.5	-12.5, 8.3	41.7, 75.0	-25.0, -8.3
	Min, Max	17, 100	-42, 33	17, 83	-33, 8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	94.4 (14.79)		78.4 (18.41)	
	Median	100.0		83.3	
	Q1, Q3	100.0, 100.0		66.7, 100.0	
	Min, Max	50, 100		33, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	93.3 (11.65)	0.0 (17.57)	75.6 (28.78)	-1.1 (17.21)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-33, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	91.7 (21.15)	-1.7 (9.46)	80.6 (17.16)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-8.3, 0.0
	Min, Max	33, 100	-17, 17	50, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	94.4 (11.79)	1.9 (10.02)	80.6 (24.45)	-1.4 (20.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	75.0, 100.0	0.0, 16.7
	Min, Max	67, 100	-17, 17	33, 100	-50, 17
Cycle 5	n	8	8	11	11
	Mean (SD)	87.5 (23.15)	-6.3 (17.68)	83.3 (26.87)	0.0 (27.89)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 16.7
	Min, Max	50, 100	-50, 0	33, 100	-50, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	92.9 (18.90)	0.0 (0.00)	83.3 (16.67)	0.0 (16.67)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	50, 100	-33, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	90.5 (16.27)	-2.4 (15.00)	90.5 (13.11)	7.1 (16.27)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	67, 100	-33, 17	67, 100	-17, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	87.5 (25.00)	0.0 (0.00)	83.3 (25.82)	0.0 (18.26)
	Median	100.0	0.0	91.7	0.0
	Q1, Q3	75.0, 100.0	0.0, 0.0	83.3, 100.0	0.0, 16.7
	Min, Max	50, 100	0, 0	33, 100	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	77.8 (38.49)	-5.6 (9.62)	73.3 (27.89)	-6.7 (27.89)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	33.3, 100.0	-16.7, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	33, 100	-17, 0	33, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	77.8 (19.25)	0.0 (0.00)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	66.7 (47.14)	-16.7 (23.57)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 16.7	33.3, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 17	33, 100	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	88.9 (9.62)	5.6 (25.46)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	83.3, 100.0	-16.7, 33.3	66.7, 100.0	0.0, 0.0
	Min, Max	83, 100	-17, 33	67, 100	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	5.6 (9.62)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	94.4 (9.62)	11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 33.3	66.7, 100.0	-33.3, 0.0
	Min, Max	83, 100	0, 33	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	88.9 (19.25)	0.0 (0.00)
	Median	83.3	8.3	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	83.3 (23.57)	0.0 (0.00)
	Median	83.3	8.3	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 17	67, 100	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	8.3 (11.79)	66.7 (47.14)	-16.7 (23.57)
	Median	83.3	8.3	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 16.7	33.3, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 17	33, 100	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	100.0 (NE)	0.0 (NE)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	100, 100	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	83.3 (16.67)	0.0 (16.67)	100.0 (NE)	0.0 (NE)
	Median	83.3	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-16.7, 16.7	100.0, 100.0	0.0, 0.0
	Min, Max	67, 100	-17, 17	100, 100	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	100.0 (NE)	0.0 (NE)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	100, 100	0, 0	100, 100	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	83.3 (NE)	-16.7 (NE)
	Median	66.7	-33.3	83.3	-16.7
	Q1, Q3	66.7, 66.7	-33.3, -33.3	83.3, 83.3	-16.7, -16.7
	Min, Max	67, 67	-33, -33	83, 83	-17, -17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			100.0 (NE)	0.0 (NE)
	Median			100.0	0.0
	Q1, Q3			100.0, 100.0	0.0, 0.0
	Min, Max			100, 100	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	83.3 (NE)	-16.7 (NE)	66.7 (NE)	-33.3 (NE)
	Median	83.3	-16.7	66.7	-33.3
	Q1, Q3	83.3, 83.3	-16.7, -16.7	66.7, 66.7	-33.3, -33.3
	Min, Max	83, 83	-17, -17	67, 67	-33, -33
Cycle 48	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 64	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		
Cycle 68	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		
Cycle 70	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
End of Treatment	n	10	10	16	16
	Mean (SD)	96.7 (7.03)	3.3 (13.15)	72.9 (27.13)	-6.3 (19.12)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-25.0, 0.0
	Min, Max	83, 100	-17, 33	0, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Cognitive functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	83.3 (23.57)	-11.1 (19.25)	61.8 (27.49)	-16.7 (19.54)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	-25.0, 0.0	33.3, 83.3	-33.3, 0.0
	Min, Max	33, 100	-50, 17	0, 100	-50, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	83.3 (21.32)		80.4 (17.91)	
	Median	91.7		83.3	
	Q1, Q3	66.7, 100.0		66.7, 100.0	
	Min, Max	33, 100		50, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	85.0 (18.34)	0.0 (15.71)	68.9 (28.08)	-10.0 (23.40)
	Median	91.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-16.7, 0.0	50.0, 100.0	-16.7, 0.0
	Min, Max	50, 100	-17, 33	0, 100	-67, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	90.0 (17.92)	5.0 (11.25)	76.4 (21.86)	-6.9 (19.41)
	Median	100.0	0.0	75.0	-8.3
	Q1, Q3	83.3, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	50, 100	0, 33	33, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	85.2 (17.57)	0.0 (16.67)	69.4 (25.46)	-13.9 (19.89)
	Median	100.0	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 0.0	50.0, 91.7	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	91.7 (15.43)	0.0 (17.82)	71.2 (24.82)	-15.2 (22.92)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	83.3, 100.0	0.0, 0.0	50.0, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 33	33, 100	-50, 17
Cycle 6	n	7	7	9	9
	Mean (SD)	95.2 (12.60)	4.8 (12.60)	83.3 (16.67)	-5.6 (18.63)
	Median	100.0	0.0	83.3	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 33	67, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	85.7 (17.82)	-4.8 (23.00)	88.1 (15.85)	-2.4 (20.25)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	-33, 33	67, 100	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (43.03)	-41.7 (41.94)	83.3 (27.89)	-5.6 (25.09)
	Median	50.0	-33.3	100.0	0.0
	Q1, Q3	16.7, 83.3	-66.7, -16.7	66.7, 100.0	-33.3, 0.0
	Min, Max	0, 100	-100, 0	33, 100	-33, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	83.3 (28.87)	-3.3 (24.72)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	83.3, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	33, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	88.9 (19.25)	0.0 (0.00)	88.9 (19.25)	0.0 (0.00)
	Median	100.0	0.0	100.0	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	0.0, 0.0
	Min, Max	67, 100	0, 0	67, 100	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	58.3 (35.36)	-25.0 (11.79)
	Median	66.7	0.0	58.3	-25.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	33.3, 83.3	-33.3, -16.7
	Min, Max	67, 100	-33, 0	33, 83	-33, -17
Cycle 18	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	66.7 (33.33)	-22.2 (38.49)	83.3 (16.67)	-5.6 (9.62)
	Median	66.7	0.0	83.3	0.0
	Q1, Q3	33.3, 100.0	-66.7, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	33, 100	-67, 0	67, 100	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	77.8 (19.25)	-11.1 (19.25)	77.8 (19.25)	-11.1 (19.25)
	Median	66.7	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	-33.3, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	-33, 0	67, 100	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	77.8 (19.25)	-11.1 (19.25)
	Median	83.3	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	-33.3, 0.0
	Min, Max	67, 100	0, 0	67, 100	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	83.3 (16.67)	-5.6 (9.62)
	Median	83.3	0.0	83.3	0.0
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 100.0	-16.7, 0.0
	Min, Max	67, 100	0, 0	67, 100	-17, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	83.3 (23.57)	0.0 (0.00)	66.7 (0.00)	-16.7 (23.57)
	Median	83.3	0.0	66.7	-16.7
	Q1, Q3	66.7, 100.0	0.0, 0.0	66.7, 66.7	-33.3, 0.0
	Min, Max	67, 100	0, 0	67, 67	-33, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	66.7 (0.00)	-16.7 (23.57)	75.0 (11.79)	-8.3 (11.79)
	Median	66.7	-16.7	75.0	-8.3
	Q1, Q3	66.7, 66.7	-33.3, 0.0	66.7, 83.3	-16.7, 0.0
	Min, Max	67, 67	-33, 0	67, 83	-17, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	66.7 (33.33)	-22.2 (38.49)	100.0 (NE)	0.0 (NE)
	Median	66.7	0.0	100.0	0.0
	Q1, Q3	33.3, 100.0	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 100	-67, 0	100, 100	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	55.6 (19.25)	-33.3 (33.33)	100.0 (NE)	0.0 (NE)
	Median	66.7	-33.3	100.0	0.0
	Q1, Q3	33.3, 66.7	-66.7, 0.0	100.0, 100.0	0.0, 0.0
	Min, Max	33, 67	-67, 0	100, 100	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	66.7 (NE)	-33.3 (NE)
	Median	100.0	0.0	66.7	-33.3
	Q1, Q3	100.0, 100.0	0.0, 0.0	66.7, 66.7	-33.3, -33.3
	Min, Max	100, 100	0, 0	67, 67	-33, -33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 40	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	66.7 (NE)	-33.3 (NE)
	Median	33.3	-66.7	66.7	-33.3
	Q1, Q3	33.3, 33.3	-66.7, -66.7	66.7, 66.7	-33.3, -33.3
	Min, Max	33, 33	-67, -67	67, 67	-33, -33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			66.7 (NE)	-33.3 (NE)
	Median			66.7	-33.3
	Q1, Q3			66.7, 66.7	-33.3, -33.3
	Min, Max			67, 67	-33, -33
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	66.7 (NE)	-33.3 (NE)
	Median	66.7	-33.3	66.7	-33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	66.7, 66.7	-33.3, -33.3
	Min, Max	67, 67	-33, -33	67, 67	-33, -33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		
Cycle 52	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 60	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-83.3 (NE)		
	Median	16.7	-83.3		
	Q1, Q3	16.7, 16.7	-83.3, -83.3		
	Min, Max	17, 17	-83, -83		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-100.0 (NE)		
	Median	0.0	-100.0		
	Q1, Q3	0.0, 0.0	-100.0, -100.0		
	Min, Max	0, 0	-100, -100		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 68	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 70	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
End of Treatment	n	10	10	16	16
	Mean (SD)	83.3 (22.22)	1.7 (24.15)	67.7 (33.04)	-13.5 (26.68)
	Median	100.0	0.0	66.7	0.0
	Q1, Q3	66.7, 100.0	0.0, 16.7	58.3, 100.0	-33.3, 0.0
	Min, Max	50, 100	-50, 33	0, 100	-67, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Social functioning

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	65.3 (29.69)	-18.1 (29.69)	50.0 (27.00)	-30.4 (18.85)
	Median	66.7	-16.7	50.0	-33.3
	Q1, Q3	50.0, 91.7	-25.0, 0.0	33.3, 66.7	-50.0, -16.7
	Min, Max	0, 100	-100, 17	0, 100	-67, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	24.1 (31.72)		33.3 (22.57)	
	Median	5.6		33.3	
	Q1, Q3	0.0, 50.0		22.2, 44.4	
	Min, Max	0, 89		0, 78	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.6 (21.72)	-8.9 (23.31)	41.5 (26.05)	9.6 (18.24)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-11.1, 0.0	22.2, 44.4	0.0, 22.2
	Min, Max	0, 56	-67, 22	0, 100	-11, 56
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (25.01)	-4.4 (15.89)	39.8 (23.43)	8.3 (13.50)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 44.4	-11.1, 0.0	27.8, 55.6	0.0, 16.7
	Min, Max	0, 67	-44, 11	11, 89	-11, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	23.5 (30.65)	-1.2 (10.31)	42.6 (28.36)	11.1 (22.72)
	Median	11.1	0.0	44.4	5.6
	Q1, Q3	0.0, 33.3	0.0, 0.0	16.7, 61.1	0.0, 33.3
	Min, Max	0, 89	-22, 11	0, 89	-33, 44
Cycle 5	n	8	8	11	11
	Mean (SD)	15.3 (25.85)	-5.6 (10.29)	32.3 (26.04)	5.1 (20.71)
	Median	0.0	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	-11.1, 0.0	11.1, 44.4	0.0, 22.2
	Min, Max	0, 67	-22, 0	0, 89	-44, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	12.7 (25.20)	1.6 (4.20)	29.6 (21.52)	1.2 (15.16)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 22.2	0.0, 0.0	22.2, 33.3	-11.1, 11.1
	Min, Max	0, 67	0, 11	0, 78	-22, 22

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	25.4 (36.69)	1.6 (7.67)	11.1 (15.71)	-12.7 (16.27)
	Median	0.0	0.0	0.0	-11.1
	Q1, Q3	0.0, 77.8	0.0, 11.1	0.0, 33.3	-22.2, 0.0
	Min, Max	0, 78	-11, 11	0, 33	-44, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	50.0 (46.70)	8.3 (18.98)	18.5 (30.36)	-9.3 (25.74)
	Median	50.0	5.6	5.6	-11.1
	Q1, Q3	11.1, 88.9	-5.6, 22.2	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 100	-11, 33	0, 78	-44, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	40.7 (52.51)	-11.1 (50.92)	33.3 (15.71)	0.0 (11.11)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	-66.7, 33.3	33.3, 33.3	-11.1, 11.1
	Min, Max	0, 100	-67, 33	11, 56	-11, 11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (11.11)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-22.2, 0.0
	Min, Max	0, 33	-56, 0	11, 33	-22, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	29.6 (33.95)	-22.2 (38.49)	33.3 (31.43)	0.0 (15.71)
	Median	22.2	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	11.1, 55.6	-11.1, 11.1
	Min, Max	0, 67	-67, 0	11, 56	-11, 11
Cycle 18	n	3	3	3	3
	Mean (SD)	37.0 (39.02)	-14.8 (16.97)	25.9 (16.97)	-7.4 (6.42)
	Median	33.3	-11.1	22.2	-11.1
	Q1, Q3	0.0, 77.8	-33.3, 0.0	11.1, 44.4	-11.1, 0.0
	Min, Max	0, 78	-33, 0	11, 44	-11, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-29.6 (27.96)	22.2 (11.11)	-11.1 (0.00)
	Median	33.3	-33.3	22.2	-11.1
	Q1, Q3	0.0, 33.3	-55.6, 0.0	11.1, 33.3	-11.1, -11.1
	Min, Max	0, 33	-56, 0	11, 33	-11, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (22.22)	-29.6 (25.66)	37.0 (6.42)	3.7 (6.42)
	Median	22.2	-44.4	33.3	0.0
	Q1, Q3	0.0, 44.4	-44.4, 0.0	33.3, 44.4	0.0, 11.1
	Min, Max	0, 44	-44, 0	33, 44	0, 11
Cycle 24	n	2	2	3	3
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	37.0 (12.83)	3.7 (16.97)
	Median	11.1	-22.2	44.4	0.0
	Q1, Q3	0.0, 22.2	-44.4, 0.0	22.2, 44.4	-11.1, 22.2
	Min, Max	0, 22	-44, 0	22, 44	-11, 22

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	11.1 (15.71)	-22.2 (31.43)	25.9 (16.97)	-7.4 (6.42)
	Median	11.1	-22.2	22.2	-11.1
	Q1, Q3	0.0, 22.2	-44.4, 0.0	11.1, 44.4	-11.1, 0.0
	Min, Max	0, 22	-44, 0	11, 44	-11, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	38.9 (7.86)	5.6 (7.86)
	Median	16.7	-16.7	38.9	5.6
	Q1, Q3	0.0, 33.3	-33.3, 0.0	33.3, 44.4	0.0, 11.1
	Min, Max	0, 33	-33, 0	33, 44	0, 11
Cycle 30	n	2	2	2	2
	Mean (SD)	33.3 (0.00)	-44.4 (15.71)	27.8 (23.57)	-5.6 (7.86)
	Median	33.3	-44.4	27.8	-5.6
	Q1, Q3	33.3, 33.3	-55.6, -33.3	11.1, 44.4	-11.1, 0.0
	Min, Max	33, 33	-56, -33	11, 44	-11, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	40.7 (52.51)	-11.1 (29.40)	22.2 (NE)	0.0 (NE)
	Median	22.2	0.0	22.2	0.0
	Q1, Q3	0.0, 100.0	-44.4, 11.1	22.2, 22.2	0.0, 0.0
	Min, Max	0, 100	-44, 11	22, 22	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	37.0 (39.02)	-14.8 (16.97)	33.3 (NE)	11.1 (NE)
	Median	33.3	-11.1	33.3	11.1
	Q1, Q3	0.0, 77.8	-33.3, 0.0	33.3, 33.3	11.1, 11.1
	Min, Max	0, 78	-33, 0	33, 33	11, 11
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	22.2 (NE)	0.0 (NE)
	Median	0.0	0.0	22.2	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	22.2, 22.2	0.0, 0.0
	Min, Max	0, 0	0, 0	22, 22	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	0.0 (NE)
	Median			22.2	0.0
	Q1, Q3			22.2, 22.2	0.0, 0.0
	Min, Max			22, 22	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	44.4 (NE)	-44.4 (NE)	22.2 (NE)	0.0 (NE)
	Median	44.4	-44.4	22.2	0.0
	Q1, Q3	44.4, 44.4	-44.4, -44.4	22.2, 22.2	0.0, 0.0
	Min, Max	44, 44	-44, -44	22, 22	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	11.1 (NE)
	Median			33.3	11.1
	Q1, Q3			33.3, 33.3	11.1, 11.1
	Min, Max			33, 33	11, 11
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-22.2 (NE)	33.3 (NE)	11.1 (NE)
	Median	66.7	-22.2	33.3	11.1
	Q1, Q3	66.7, 66.7	-22.2, -22.2	33.3, 33.3	11.1, 11.1
	Min, Max	67, 67	-22, -22	33, 33	11, 11
Cycle 48	n	1	1	0	0
	Mean (SD)	77.8 (NE)	-11.1 (NE)		
	Median	77.8	-11.1		
	Q1, Q3	77.8, 77.8	-11.1, -11.1		
	Min, Max	78, 78	-11, -11		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	55.6 (NE)	-33.3 (NE)		
	Median	55.6	-33.3		
	Q1, Q3	55.6, 55.6	-33.3, -33.3		
	Min, Max	56, 56	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-22.2 (NE)		
	Median	66.7	-22.2		
	Q1, Q3	66.7, 66.7	-22.2, -22.2		
	Min, Max	67, 67	-22, -22		
Cycle 56	n	1	1	0	0
	Mean (SD)	44.4 (NE)	-44.4 (NE)		
	Median	44.4	-44.4		
	Q1, Q3	44.4, 44.4	-44.4, -44.4		
	Min, Max	44, 44	-44, -44		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	44.4 (NE)	-44.4 (NE)		
	Median	44.4	-44.4		
	Q1, Q3	44.4, 44.4	-44.4, -44.4		
	Min, Max	44, 44	-44, -44		
Cycle 60	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-55.6 (NE)		
	Median	33.3	-55.6		
	Q1, Q3	33.3, 33.3	-55.6, -55.6		
	Min, Max	33, 33	-56, -56		
Cycle 64	n	1	1	0	0
	Mean (SD)	88.9 (NE)	0.0 (NE)		
	Median	88.9	0.0		
	Q1, Q3	88.9, 88.9	0.0, 0.0		
	Min, Max	89, 89	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	77.8 (NE)	-11.1 (NE)		
	Median	77.8	-11.1		
	Q1, Q3	77.8, 77.8	-11.1, -11.1		
	Min, Max	78, 78	-11, -11		
Cycle 68	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-22.2 (NE)		
	Median	66.7	-22.2		
	Q1, Q3	66.7, 66.7	-22.2, -22.2		
	Min, Max	67, 67	-22, -22		
Cycle 70	n	1	1	0	0
	Mean (SD)	55.6 (NE)	-33.3 (NE)		
	Median	55.6	-33.3		
	Q1, Q3	55.6, 55.6	-33.3, -33.3		
	Min, Max	56, 56	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	88.9 (NE)	0.0 (NE)		
	Median	88.9	0.0		
	Q1, Q3	88.9, 88.9	0.0, 0.0		
	Min, Max	89, 89	0, 0		
End of Treatment	n	10	10	16	16
	Mean (SD)	24.4 (23.31)	0.0 (18.14)	41.7 (23.83)	8.3 (16.97)
	Median	22.2	0.0	33.3	5.6
	Q1, Q3	0.0, 33.3	-11.1, 11.1	27.8, 66.7	0.0, 22.2
	Min, Max	0, 78	-33, 22	0, 89	-22, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Fatigue

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.0 (36.22)	13.9 (13.50)	58.8 (26.58)	25.5 (15.60)
	Median	22.2	11.1	55.6	33.3
	Q1, Q3	11.1, 61.1	5.6, 22.2	44.4, 77.8	22.2, 33.3
	Min, Max	0, 100	-11, 33	11, 100	0, 56

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	5.6 (10.86)		8.8 (16.79)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 8.3		0.0, 16.7	
	Min, Max	0, 33		0, 50	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (13.15)	20.0 (20.12)	10.0 (13.80)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 17	0, 67	-17, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-1.7 (9.46)	15.3 (20.67)	12.5 (23.70)
	Median	0.0	0.0	8.3	8.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 25.0	0.0, 25.0
	Min, Max	0, 17	-17, 17	0, 67	-17, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (18.84)	3.7 (13.89)	11.1 (12.97)	8.3 (15.08)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 50	-17, 33	0, 33	-17, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (12.60)	2.1 (13.91)	16.7 (19.72)	13.6 (22.13)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-17, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	7.1 (13.11)	4.8 (12.60)	22.2 (18.63)	18.5 (21.15)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 50	-17, 50

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (19.25)	7.1 (8.91)	2.4 (15.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 16.7	-16.7, 16.7
	Min, Max	0, 33	-33, 33	0, 17	-17, 17
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-4.2 (28.46)	5.6 (13.61)	0.0 (10.54)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-25.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	-17, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (25.46)	10.0 (22.36)	3.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 17	0, 50	-17, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (19.25)	16.7 (23.57)	8.3 (11.79)
	Median	0.0	0.0	16.7	8.3
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	11.1 (19.25)	5.6 (9.62)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 33	0, 17
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (9.62)	5.6 (9.62)
	Median	0.0	-8.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 17	0, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	16.7 (16.67)	11.1 (9.62)
	Median	0.0	-8.3	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 33	0, 17
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	16.7 (23.57)	8.3 (11.79)
	Median	0.0	-8.3	16.7	8.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-17, 0	0, 33	0, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-25.0 (11.79)	8.3 (11.79)	0.0 (0.00)
	Median	0.0	-25.0	8.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, -16.7	0.0, 16.7	0.0, 0.0
	Min, Max	0, 0	-33, -17	0, 17	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-16.7 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	16.7 (NE)	16.7 (NE)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	16.7, 16.7	16.7, 16.7
	Min, Max	0, 0	0, 0	17, 17	17, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-33.3 (NE)	16.7 (NE)	16.7 (NE)
	Median	0.0	-33.3	16.7	16.7
	Q1, Q3	0.0, 0.0	-33.3, -33.3	16.7, 16.7	16.7, 16.7
	Min, Max	0, 0	-33, -33	17, 17	17, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-33.3 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, -33	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 60	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 68	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 70	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-16.7 (NE)		
	Median	16.7	-16.7		
	Q1, Q3	16.7, 16.7	-16.7, -16.7		
	Min, Max	17, 17	-17, -17		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-16.7 (NE)		
	Median	16.7	-16.7		
	Q1, Q3	16.7, 16.7	-16.7, -16.7		
	Min, Max	17, 17	-17, -17		
End of Treatment	n	10	10	16	16
	Mean (SD)	6.7 (16.10)	1.7 (18.34)	15.6 (15.48)	6.3 (21.84)
	Median	0.0	0.0	16.7	8.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-17, 50	0, 33	-50, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Nausea and vomiting

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	11.1 (20.52)	5.6 (16.41)	35.3 (19.44)	26.5 (18.69)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 16.7	0.0, 8.3	16.7, 50.0	16.7, 33.3
	Min, Max	0, 50	-17, 50	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	18.1 (28.83)		24.5 (31.25)	
	Median	0.0		16.7	
	Q1, Q3	0.0, 25.0		0.0, 33.3	
	Min, Max	0, 83		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.0 (11.25)	-13.3 (26.99)	24.4 (33.25)	1.1 (29.19)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 0.0
	Min, Max	0, 33	-83, 0	0, 100	-50, 83
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (7.03)	-15.0 (24.15)	26.4 (27.02)	5.6 (32.05)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-8.3, 16.7
	Min, Max	0, 17	-67, 0	0, 83	-50, 83

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	13.0 (28.60)	-7.4 (12.11)	20.8 (23.70)	0.0 (26.59)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 83	-33, 0	0, 83	-50, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	6.3 (17.68)	-8.3 (12.60)	21.2 (24.82)	6.1 (22.70)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-33, 0	0, 83	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (16.67)	20.4 (24.69)	5.6 (25.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 33	0, 67	-33, 50

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.13)	-11.9 (24.93)	7.1 (13.11)	2.4 (20.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-67, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (9.62)	-16.7 (33.33)	11.1 (27.22)	5.6 (32.77)
	Median	8.3	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 17	-67, 0	0, 67	-33, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	16.7 (28.87)	-16.7 (60.09)	20.0 (21.73)	13.3 (21.73)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 50.0	-83.3, 33.3	0.0, 33.3	0.0, 16.7
	Min, Max	0, 50	-83, 33	0, 50	0, 50

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (16.67)	16.7 (16.67)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	-16.7	16.7	16.7
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (9.62)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-17, 0	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (44.10)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	-16.7	33.3	33.3
	Q1, Q3	0.0, 0.0	-83.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-83, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	27.8 (48.11)	-5.6 (9.62)	22.2 (9.62)	22.2 (9.62)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 83.3	-16.7, 0.0	16.7, 33.3	16.7, 33.3
	Min, Max	0, 83	-17, 0	17, 33	17, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	-8.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-8.3 (11.79)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	-8.3	16.7	16.7
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-17, 0	0, 33	0, 33
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-33.3 (23.57)	25.0 (11.79)	25.0 (11.79)
	Median	16.7	-33.3	25.0	25.0
	Q1, Q3	0.0, 33.3	-50.0, -16.7	16.7, 33.3	16.7, 33.3
	Min, Max	0, 33	-50, -17	17, 33	17, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	0.0 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-17, 17	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	16.7 (28.87)	-16.7 (16.67)	0.0 (NE)	0.0 (NE)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 50	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-50.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	-50.0	33.3	33.3
	Q1, Q3	33.3, 33.3	-50.0, -50.0	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	-50, -50	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-50.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	-50.0	33.3	33.3
	Q1, Q3	33.3, 33.3	-50.0, -50.0	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	-50, -50	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-33.3 (NE)		
	Median	50.0	-33.3		
	Q1, Q3	50.0, 50.0	-33.3, -33.3		
	Min, Max	50, 50	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	83.3 (NE)	0.0 (NE)		
	Median	83.3	0.0		
	Q1, Q3	83.3, 83.3	0.0, 0.0		
	Min, Max	83, 83	0, 0		
Cycle 60	n	1	1	0	0
	Mean (SD)	16.7 (NE)	-66.7 (NE)		
	Median	16.7	-66.7		
	Q1, Q3	16.7, 16.7	-66.7, -66.7		
	Min, Max	17, 17	-67, -67		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		
Cycle 68	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-50.0 (NE)		
	Median	33.3	-50.0		
	Q1, Q3	33.3, 33.3	-50.0, -50.0		
	Min, Max	33, 33	-50, -50		
Cycle 70	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-33.3 (NE)		
	Median	50.0	-33.3		
	Q1, Q3	50.0, 50.0	-33.3, -33.3		
	Min, Max	50, 50	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	100.0 (NE)	16.7 (NE)		
	Median	100.0	16.7		
	Q1, Q3	100.0, 100.0	16.7, 16.7		
	Min, Max	100, 100	17, 17		
End of Treatment	n	10	10	16	16
	Mean (SD)	10.0 (14.05)	-8.3 (26.35)	36.5 (32.33)	11.5 (29.01)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	8.3, 66.7	0.0, 33.3
	Min, Max	0, 33	-50, 33	0, 100	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	26.4 (32.14)	8.3 (19.46)	50.0 (30.05)	25.5 (32.87)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 41.7	0.0, 25.0	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 83

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		15.7 (26.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	24.4 (26.63)	11.1 (20.57)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	22.2 (25.95)	8.3 (15.08)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	0, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (23.57)	8.3 (23.57)	12.1 (22.47)	3.0 (10.05)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	14.8 (24.22)	3.7 (11.11)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	25.0 (31.91)	11.1 (27.22)	5.6 (13.61)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	13.3 (18.26)	6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 67	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	22.2 (38.49)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 67	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	11.1 (19.25)	0.0 (33.33)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 33.3
	Min, Max	0, 33	0, 33	0, 33	-33, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	16.7	16.7	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	66.7 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	66.7	33.3	33.3
	Q1, Q3	66.7, 66.7	66.7, 66.7	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	67, 67	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	100.0 (NE)		
	Median	100.0	100.0		
	Q1, Q3	100.0, 100.0	100.0, 100.0		
	Min, Max	100, 100	100, 100		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	66.7 (NE)		
	Median	66.7	66.7		
	Q1, Q3	66.7, 66.7	66.7, 66.7		
	Min, Max	67, 67	67, 67		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 60	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 64	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 68	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 70	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
End of Treatment	n	10	10	16	16
	Mean (SD)	13.3 (17.21)	13.3 (17.21)	29.2 (29.50)	12.5 (20.64)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dyspnoea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	16.7 (30.15)	16.7 (30.15)	39.2 (26.97)	23.5 (22.87)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (35.77)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 50.0		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	16.7 (28.33)	-10.0 (16.10)	28.9 (30.52)	6.7 (31.37)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 100	-67, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	13.3 (17.21)	-13.3 (39.13)	25.0 (25.13)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	11.1 (16.67)	-18.5 (33.79)	16.7 (17.41)	2.8 (22.29)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	20.8 (24.80)	-12.5 (24.80)	9.1 (21.56)	0.0 (21.08)
	Median	16.7	-16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	-9.5 (16.27)	11.1 (16.67)	3.7 (20.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	28.6 (40.50)	-9.5 (16.27)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	-41.7 (41.94)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 16.7	-66.7, -16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-100, 0	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	13.3 (29.81)	6.7 (14.91)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (33.33)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	44.4 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	66.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-44.4 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	-22.2 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	33.3	-33.3	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	33.3 (33.33)	22.2 (38.49)
	Median	16.7	-16.7	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	22.2 (19.25)	11.1 (19.25)
	Median	16.7	-16.7	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 33	0, 33
Cycle 28	n	2	2	2	2
	Mean (SD)	33.3 (47.14)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	0.0	16.7	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	33.3 (0.00)	-50.0 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	33.3	-50.0	16.7	0.0
	Q1, Q3	33.3, 33.3	-66.7, -33.3	0.0, 33.3	0.0, 0.0
	Min, Max	33, 33	-67, -33	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (33.33)	-22.2 (19.25)	0.0 (NE)	0.0 (NE)
	Median	33.3	-33.3	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	44.4 (50.92)	-11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	-33.3	33.3	33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	-33, -33	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	-33.3	33.3	33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	-33, -33	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 52	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 60	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 68	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 70	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
End of Treatment	n	10	10	16	16
	Mean (SD)	30.0 (39.91)	3.3 (18.92)	25.0 (31.03)	2.1 (25.73)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-16.7, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Insomnia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	36.1 (36.12)	13.9 (17.16)	51.0 (29.15)	29.4 (28.58)
	Median	33.3	0.0	66.7	33.3
	Q1, Q3	0.0, 50.0	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 33	0, 100	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		21.6 (31.05)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	10.0 (22.50)	-10.0 (35.31)	31.1 (34.43)	6.7 (25.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	12	12
	Mean (SD)	3.3 (10.54)	-16.7 (32.39)	19.4 (22.29)	5.6 (27.83)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-11.1 (33.33)	25.0 (20.72)	11.1 (32.82)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 0	0, 67	-67, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-12.5 (39.59)	27.3 (25.03)	15.2 (34.52)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	25.9 (22.22)	11.1 (37.27)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 0	0, 67	-67, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	9.5 (16.27)	-9.5 (41.79)	14.3 (26.23)	0.0 (38.49)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-100, 33	0, 67	-67, 67
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (16.67)	-8.3 (41.94)	11.1 (27.22)	-5.6 (32.77)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	16.7, 33.3	-33.3, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	-22.2 (69.39)	13.3 (29.81)	-6.7 (36.51)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-100.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-100, 33	0, 67	-67, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-44.4 (50.92)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-16.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-66.7 (47.14)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-66.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, -33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, -33	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-44.4 (50.92)	0.0 (NE)	0.0 (NE)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	0.0 (NE)	0.0 (NE)
	Median	33.3	-66.7	0.0	0.0
	Q1, Q3	33.3, 33.3	-66.7, -66.7	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	-67, -67	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	-66.7	33.3	33.3
	Q1, Q3	33.3, 33.3	-66.7, -66.7	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	-67, -67	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 60	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 64	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 68	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
Cycle 70	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		
End of Treatment	n	10	10	16	16
	Mean (SD)	16.7 (17.57)	-3.3 (33.15)	33.3 (32.20)	10.4 (31.55)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 100	-67, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Appetite loss

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.9 (34.33)	16.7 (26.59)	49.0 (29.15)	27.5 (31.70)
	Median	33.3	16.7	33.3	33.3
	Q1, Q3	0.0, 66.7	0.0, 33.3	33.3, 66.7	0.0, 33.3
	Min, Max	0, 100	-33, 67	0, 100	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	19.4 (33.21)		17.6 (31.44)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	3.3 (29.19)	22.2 (34.88)	2.2 (23.46)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 100	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	20.0 (28.11)	0.0 (38.49)	16.7 (17.41)	13.9 (22.29)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-100, 33	0, 33	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	18.5 (33.79)	0.0 (28.87)	11.1 (16.41)	8.3 (20.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-67, 33	0, 33	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	25.0 (38.83)	16.7 (35.63)	9.1 (15.57)	9.1 (15.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	0.0, 16.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.8 (17.57)	14.8 (17.57)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	23.8 (41.79)	14.3 (26.23)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 67	0, 0	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	33.3 (47.14)	16.7 (57.74)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-16.7, 50.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	-33, 100	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	0.0 (66.67)	13.3 (29.81)	13.3 (29.81)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-66.7, 66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-67, 67	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 0	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (19.25)	0.0 (33.33)	11.1 (19.25)	11.1 (19.25)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-11.1 (50.92)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 0	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	16.7 (23.57)	16.7 (23.57)
	Median	16.7	16.7	16.7	16.7
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-16.7 (23.57)	16.7 (23.57)	16.7 (23.57)
	Median	16.7	-16.7	16.7	16.7
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 33	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-33.3 (NE)	0.0 (NE)	0.0 (NE)
	Median	33.3	-33.3	0.0	0.0
	Q1, Q3	33.3, 33.3	-33.3, -33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	-33, -33	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	100.0 (NE)	33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	100.0	33.3	33.3	33.3
	Q1, Q3	100.0, 100.0	33.3, 33.3	33.3, 33.3	33.3, 33.3
	Min, Max	100, 100	33, 33	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 56	n	1	1	0	0
	Mean (SD)	66.7 (NE)	0.0 (NE)		
	Median	66.7	0.0		
	Q1, Q3	66.7, 66.7	0.0, 0.0		
	Min, Max	67, 67	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.7 (NE)	0.0 (NE)		
	Median	66.7	0.0		
	Q1, Q3	66.7, 66.7	0.0, 0.0		
	Min, Max	67, 67	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		
Cycle 68	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		
Cycle 70	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		
End of Treatment	n	10	10	16	16
	Mean (SD)	6.7 (21.08)	-13.3 (39.13)	25.0 (35.49)	6.3 (25.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 67	-100, 33	0, 100	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Constipation

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	38.9 (42.24)	19.4 (30.01)	37.3 (30.92)	19.6 (29.01)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 83.3	0.0, 33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		7.8 (14.57)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 0.0	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (14.05)	8.9 (15.26)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 33
Cycle 3	n	10	10	12	12
	Mean (SD)	10.0 (16.10)	-3.3 (18.92)	22.2 (25.95)	11.1 (21.71)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-33, 33	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (20.03)	11.1 (21.71)	0.0 (14.21)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	8.3 (15.43)	-4.2 (11.79)	15.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	14.3 (26.23)	0.0 (0.00)	18.5 (24.22)	11.1 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 0	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (26.23)	0.0 (19.25)	9.5 (25.20)	0.0 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (33.33)	8.3 (16.67)	11.1 (27.22)	5.6 (13.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	0, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (38.49)	11.1 (19.25)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	22.2 (38.49)	11.1 (19.25)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	-33, 0	0, 67	0, 33
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-16.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	33.3 (NE)	0.0 (NE)	0.0 (NE)
	Median	33.3	33.3	0.0	0.0
	Q1, Q3	33.3, 33.3	33.3, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	33, 33	33, 33	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 60	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 66	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 68	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 70	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 72	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
End of Treatment	n	10	10	16	16
	Mean (SD)	6.7 (14.05)	-10.0 (16.10)	4.2 (11.39)	-4.2 (11.39)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Diarrhea

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Worst Post-Baseline	n	12	12	17	17
Value	Mean (SD)	22.2 (25.95)	8.3 (15.08)	23.5 (25.72)	15.7 (20.81)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-2-1-qs-chg-c30-pop1-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Global health status / QoL									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	63.19 (29.83)	10.50 (4.57)	17	57.84 (25.08)	3.23 (3.46)	7.27 (-3.30, 17.85)	0.58 (-0.26, 1.43)	0.1680

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.67 (21.84)	-1.63 (2.77)	17	87.06 (14.23)	-10.49 (2.10)	8.86 (2.53, 15.19)	1.22 (0.30, 2.14)	0.0081

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	86.11 (21.12)	6.19 (4.92)	17	79.41 (26.70)	-5.03 (3.64)	11.22 (-0.36, 22.81)	0.79 (-0.04, 1.63)	0.0570

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	72.92 (27.55)	13.40 (5.91)	17	75.49 (20.08)	0.54 (4.17)	12.87 (-0.63, 26.36)	0.79 (-0.06, 1.64)	0.0606

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-2-1-1-eff-mmrmqs-c30-pop1-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Cognitive functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	94.44 (14.79)	0.26 (4.26)	17	78.43 (18.41)	-0.92 (3.17)	1.18 (-9.14, 11.51)	0.11 (-0.80, 1.01)	0.8143

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

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[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	83.33 (21.32)	4.87 (5.70)	17	80.39 (17.91)	-7.60 (4.20)	12.47 (-0.85, 25.79)	0.78 (-0.07, 1.63)	0.0650

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

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[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	24.07 (31.72)	-6.22 (5.46)	17	33.33 (22.57)	5.60 (4.12)	-11.82 (-24.80, 1.15)	-0.76 (-1.60, 0.09)	0.0714

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	5.56 (10.86)	-3.70 (3.58)	17	8.82 (16.79)	9.08 (2.74)	-12.78 (-20.99, -4.57)	-1.35 (-2.29, -0.41)	0.0038

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

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[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	18.06 (28.83)	-14.62 (6.52)	17	24.51 (31.25)	3.66 (4.88)	-18.29 (-33.68, -2.89)	-0.99 (-1.87, -0.12)	0.0226

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	2.09 (3.77)	17	15.69 (26.66)	9.88 (2.85)	-7.78 (-16.92, 1.35)	-0.80 (-1.74, 0.15)	0.0907

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

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[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Insomnia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (35.77)	-9.34 (4.49)	17	21.57 (31.05)	3.01 (3.58)	-12.35 (-22.58, -2.13)	-1.11 (-2.06, -0.16)	0.0199

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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[a] Sample mean and SD at baseline based on the patients with baseline value.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Appetite loss									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	-13.72 (6.40)	17	21.57 (31.05)	2.38 (4.78)	-16.10 (-30.61, -1.59)	-0.97 (-1.88, -0.07)	0.0311

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Constipation									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	19.44 (33.21)	9.79 (6.80)	17	17.65 (31.44)	8.51 (5.01)	1.28 (-14.59, 17.15)	0.07 (-0.76, 0.90)	0.8684

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on change from baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Diarrhea									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-5.26 (3.06)	17	7.84 (14.57)	3.70 (2.39)	-8.96 (-15.84, -2.08)	-1.22 (-2.19, -0.25)	0.0125

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

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[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. For global health status or functional scales, positive differences favor tislelizumab+chemotherapy arm; for symptom scales, negative differences favor tislelizumab+chemotherapy arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QoL	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.808 (0.083, 7.837)	0.8539
Physical Functioning	13	2 (15.4)	NR (2.3, NE)	17	8 (47.1)	2.1 (0.9, NE)	0.213 (0.025, 1.787)	0.1173
Role Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.4 (0.7, NE)	0.177 (0.036, 0.879)	0.0198
Emotional Functioning	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	14.7 (2.2, NE)	0.000 (0.000, NE)	0.1326
Cognitive Functioning	13	2 (15.4)	NR (1.4, NE)	17	5 (29.4)	NR (2.2, NE)	0.879 (0.155, 4.997)	0.8846
Social Functioning	13	2 (15.4)	NR (2.3, NE)	17	9 (52.9)	1.5 (0.8, NE)	0.235 (0.047, 1.179)	0.0586

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Fatigue	13	3 (23.1)	NR (3.7, NE)	17	11 (64.7)	2.1 (0.7, NE)	0.327 (0.079, 1.343)	0.1083
Nausea and Vomiting	13	1 (7.7)	NR (NE, NE)	17	9 (52.9)	4.4 (0.8, NE)	0.135 (0.016, 1.117)	0.0310
Pain	13	0 (0.0)	NR (NE, NE)	17	6 (35.3)	NR (2.1, NE)	0.000 (0.000, NE)	0.0539
Dyspnoea	13	3 (23.1)	NR (1.4, NE)	17	4 (23.5)	NR (1.4, NE)	1.714 (0.268, 10.985)	0.5657
Insomnia	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	19.1 (1.4, NE)	0.171 (0.020, 1.450)	0.0687
Appetite Loss	13	2 (15.4)	NR (5.3, NE)	17	8 (47.1)	3.3 (1.4, NE)	0.352 (0.067, 1.851)	0.2032

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Constipation	13	4 (30.8)	37.6 (0.7, NE)	17	7 (41.2)	NR (0.8, NE)	0.634 (0.150, 2.673)	0.5075
Diarrhea	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.1, NE)	0.536 (0.073, 3.928)	0.5358

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

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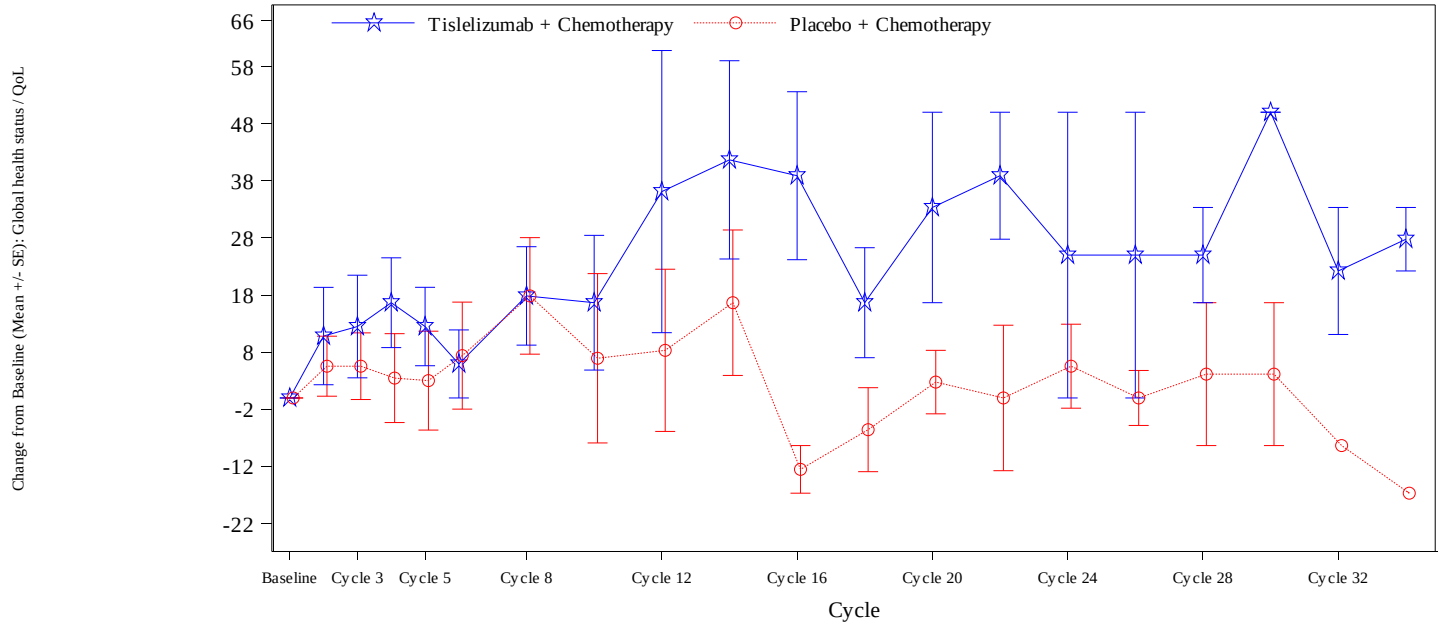
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
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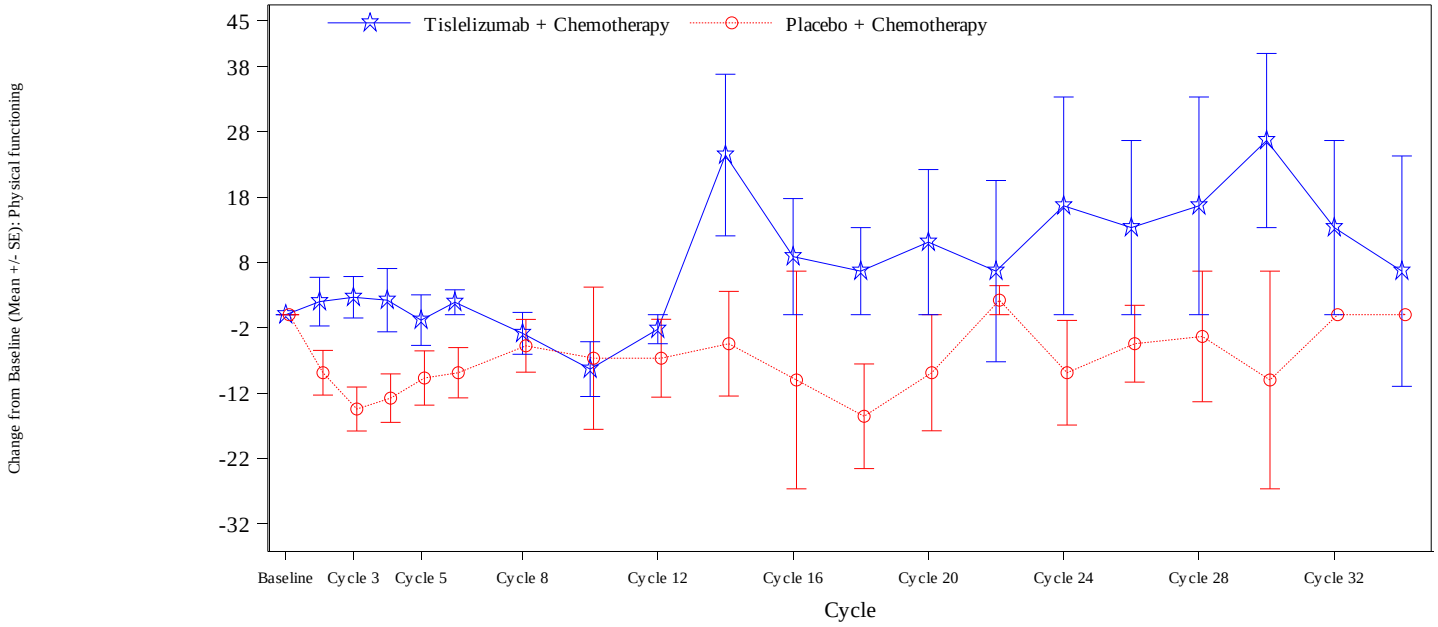
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
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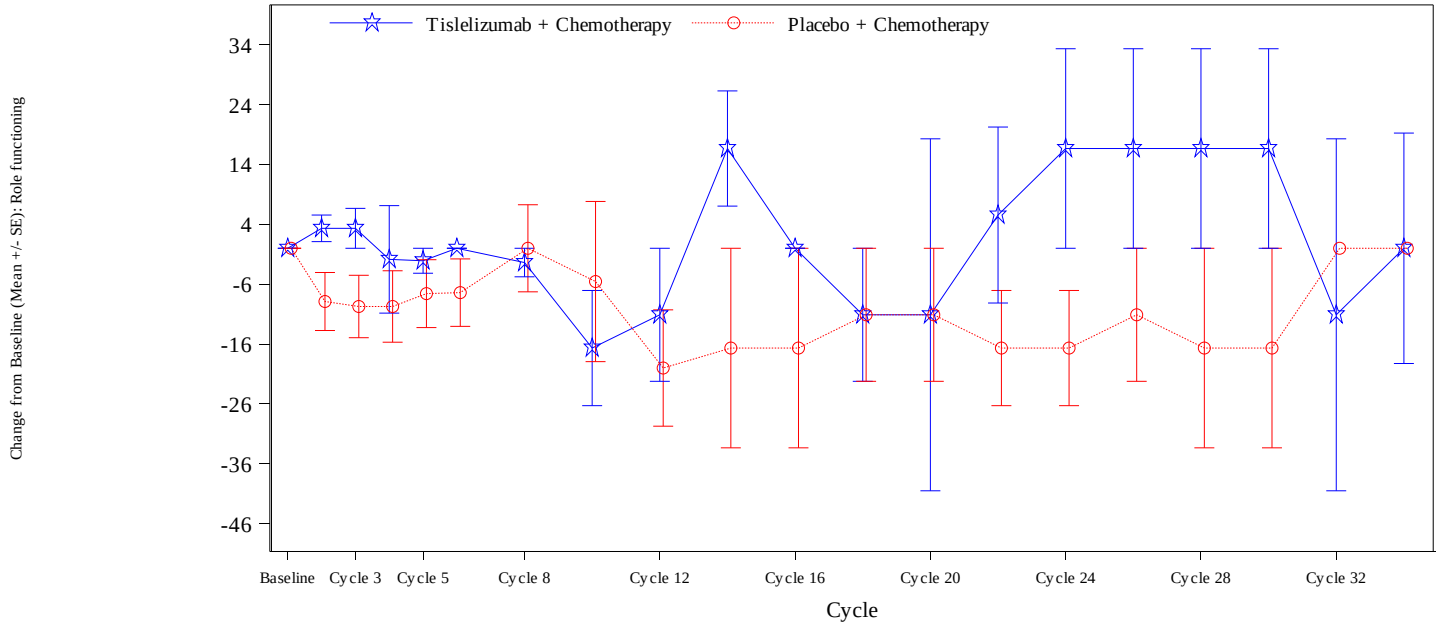

No. of Patients

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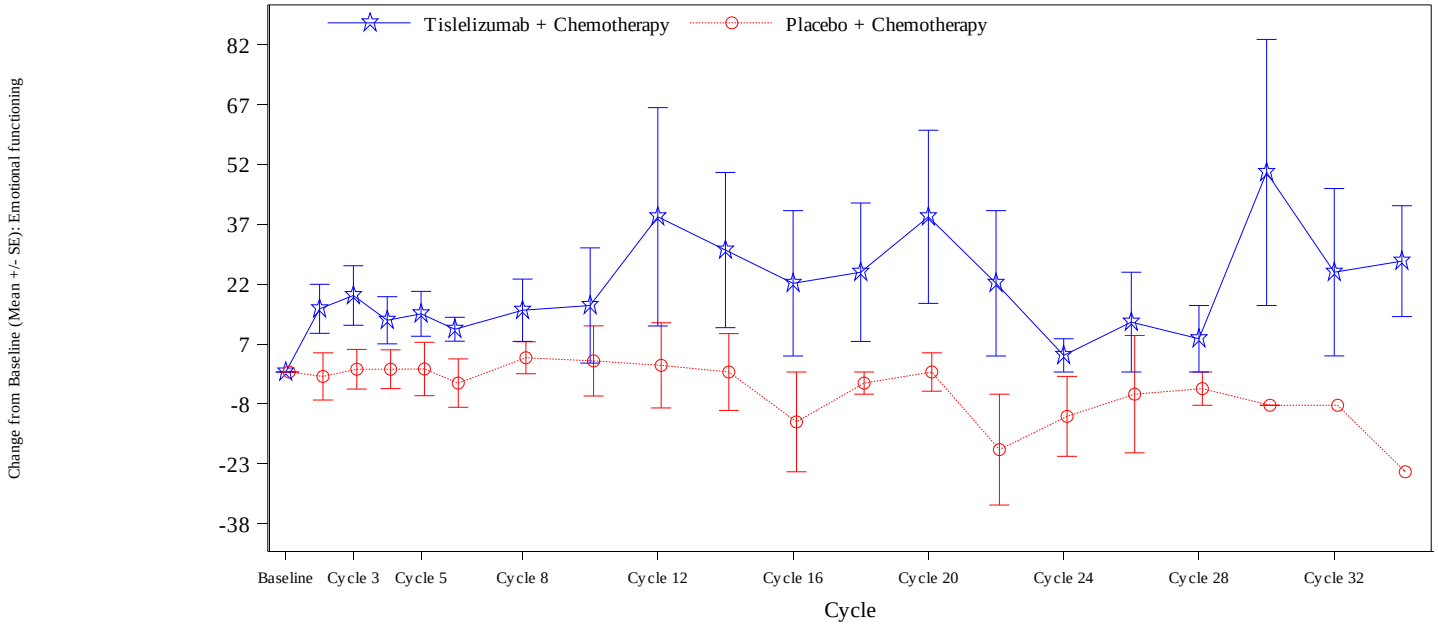
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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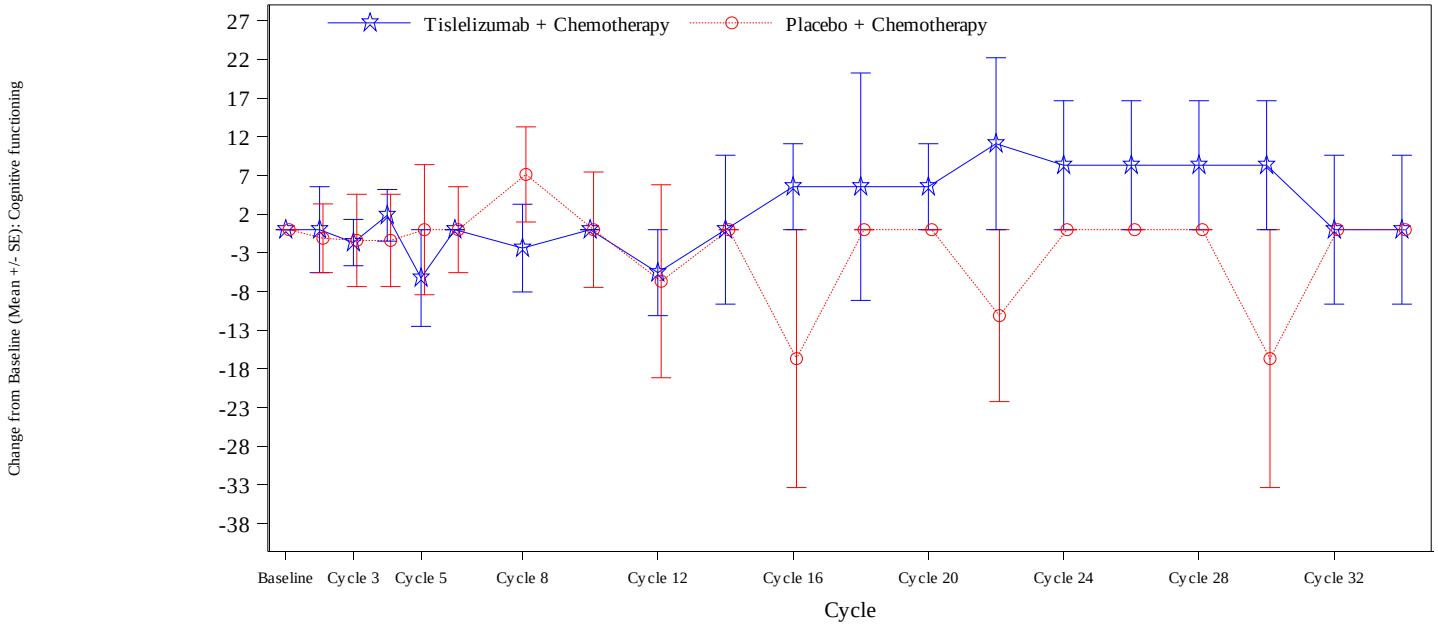

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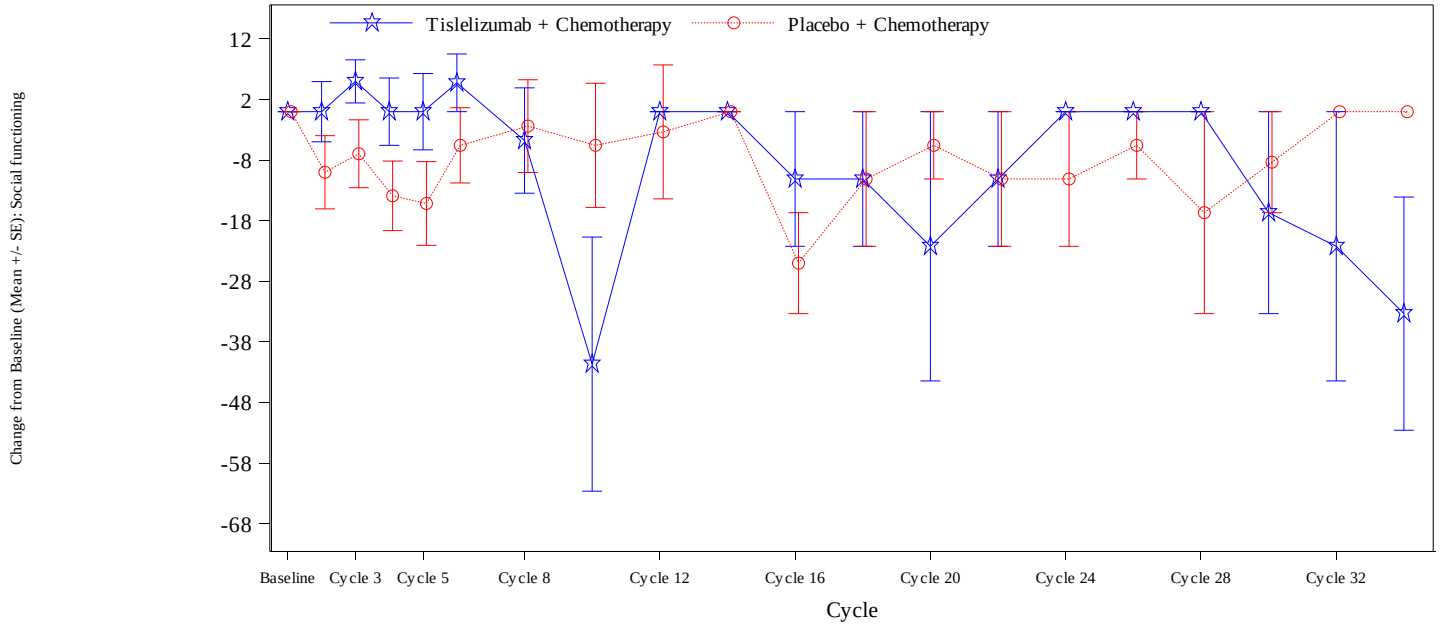

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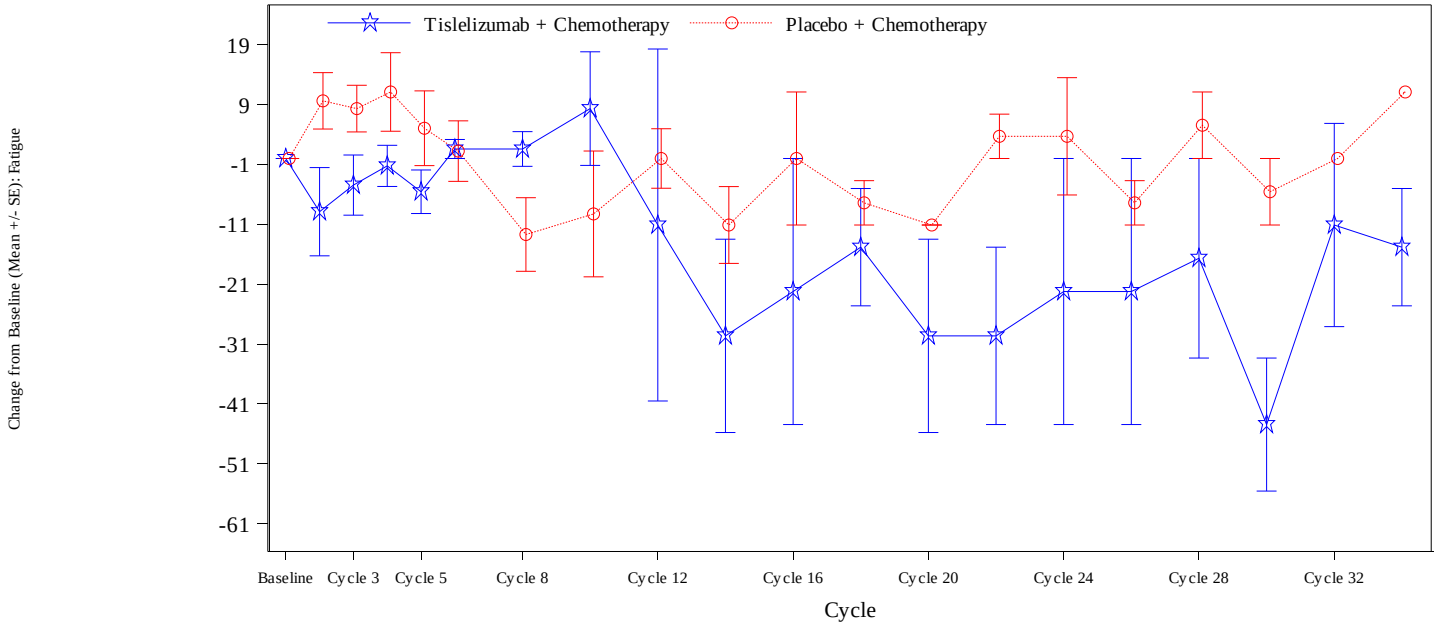

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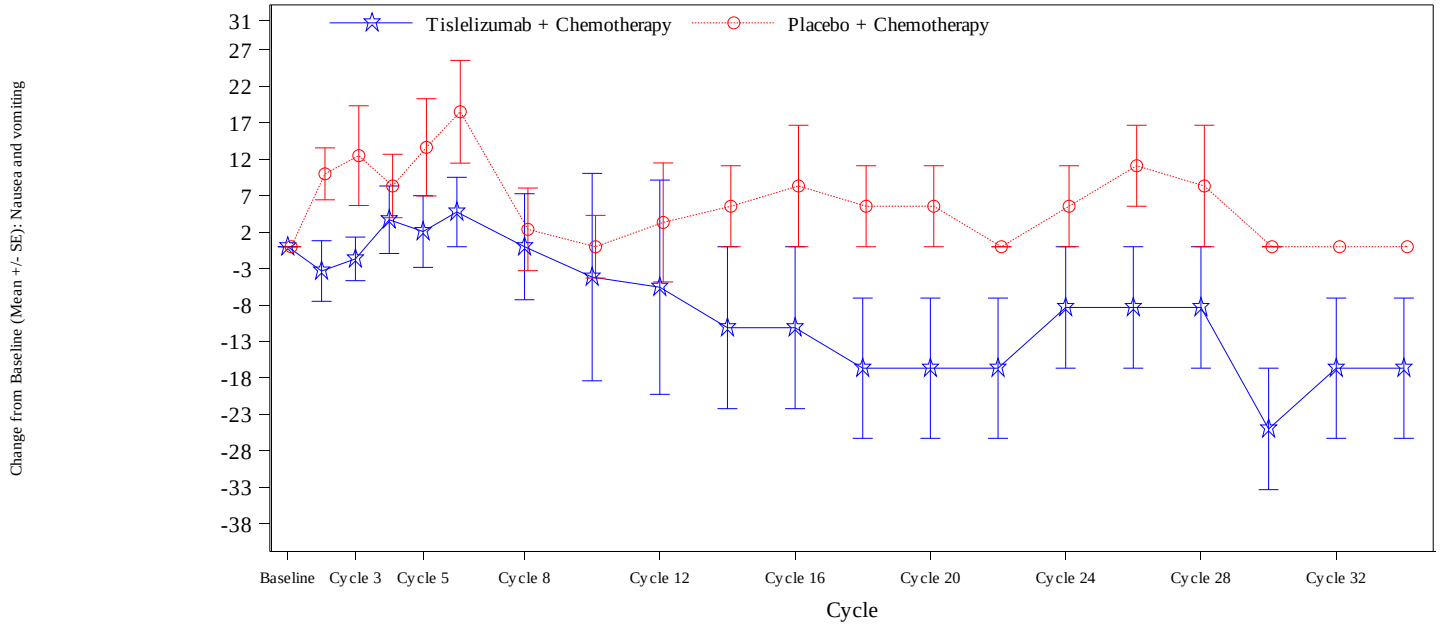

No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
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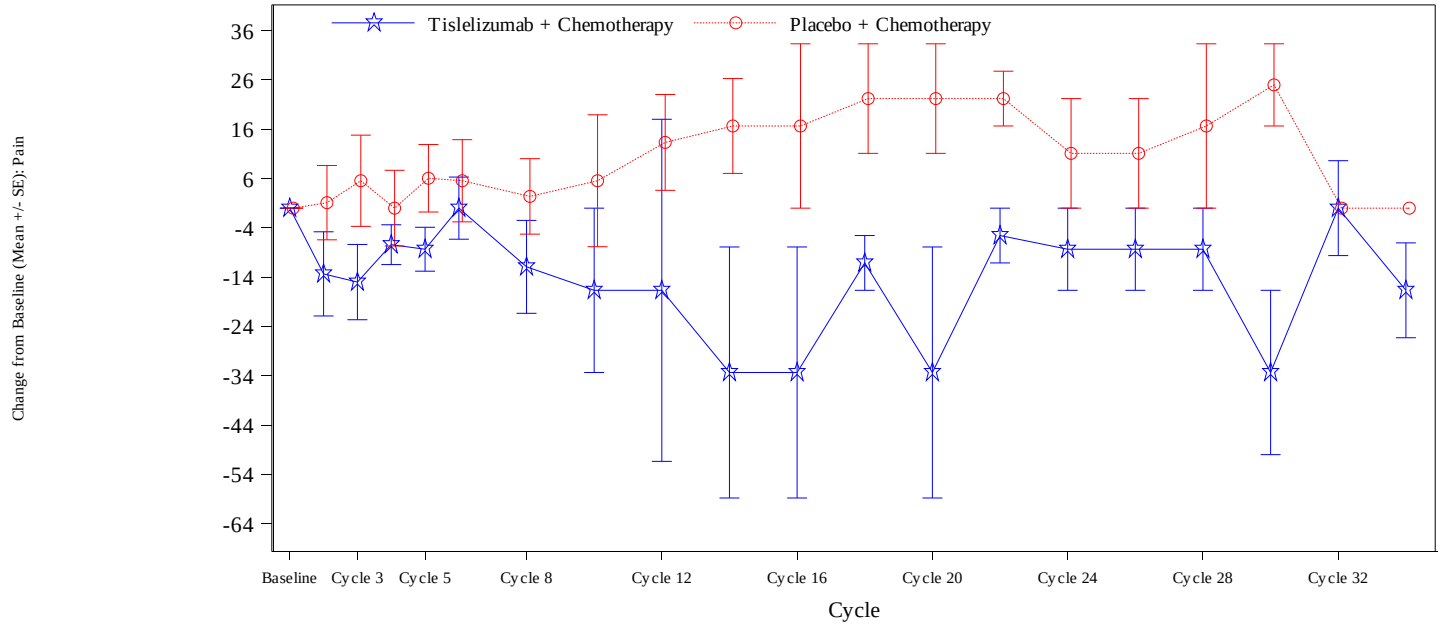
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea are deteriorations for C30.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-series.sas 26NOV2024 21:27 f-14-2-7-1-series-c30-pop1-cl.rtf

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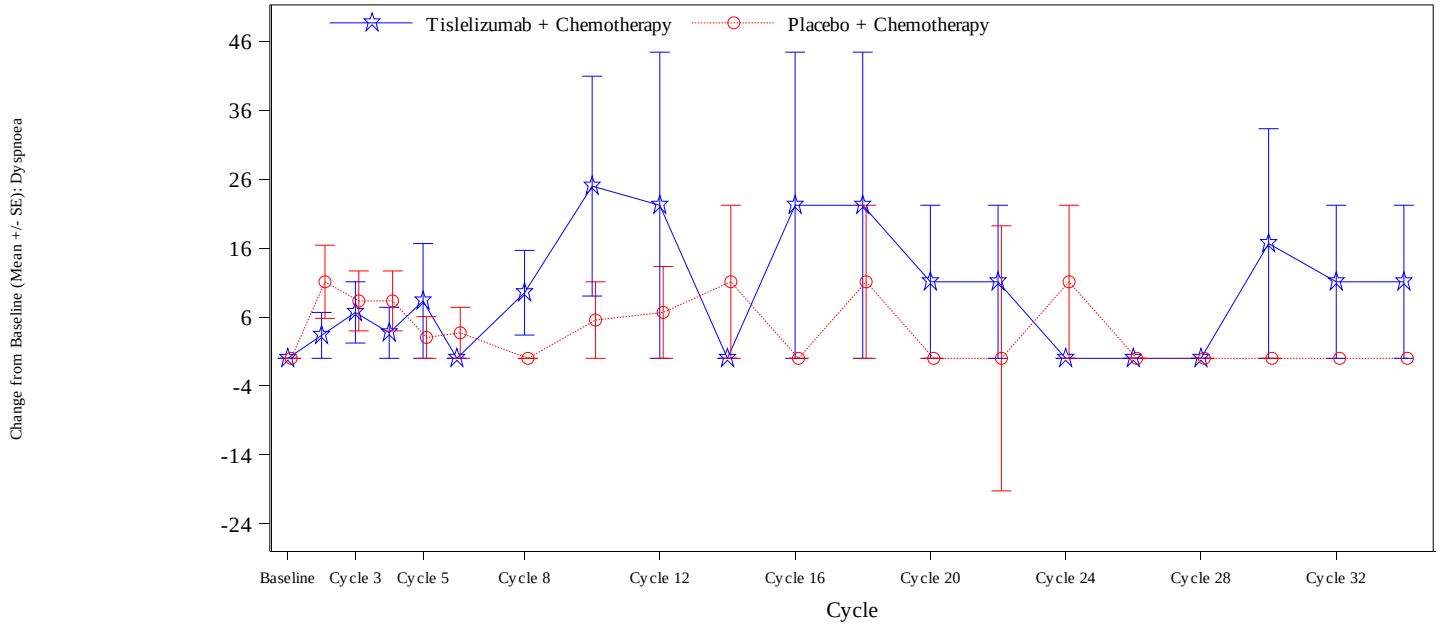

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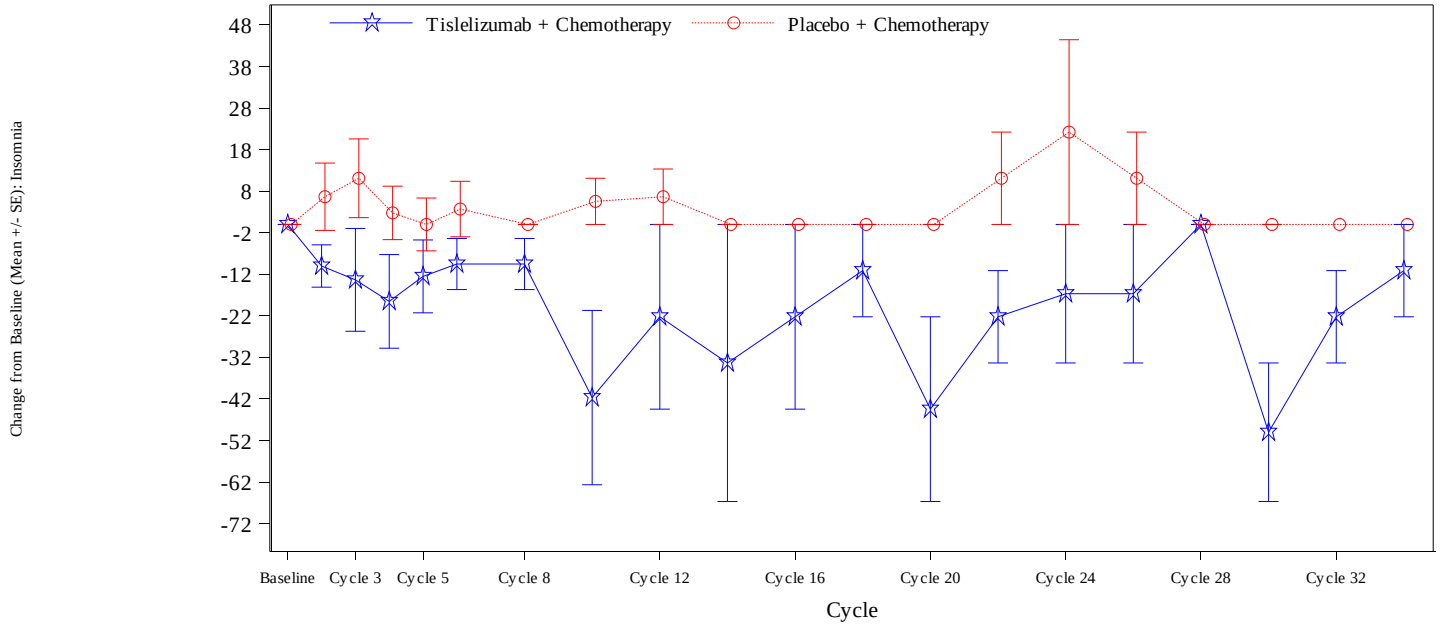

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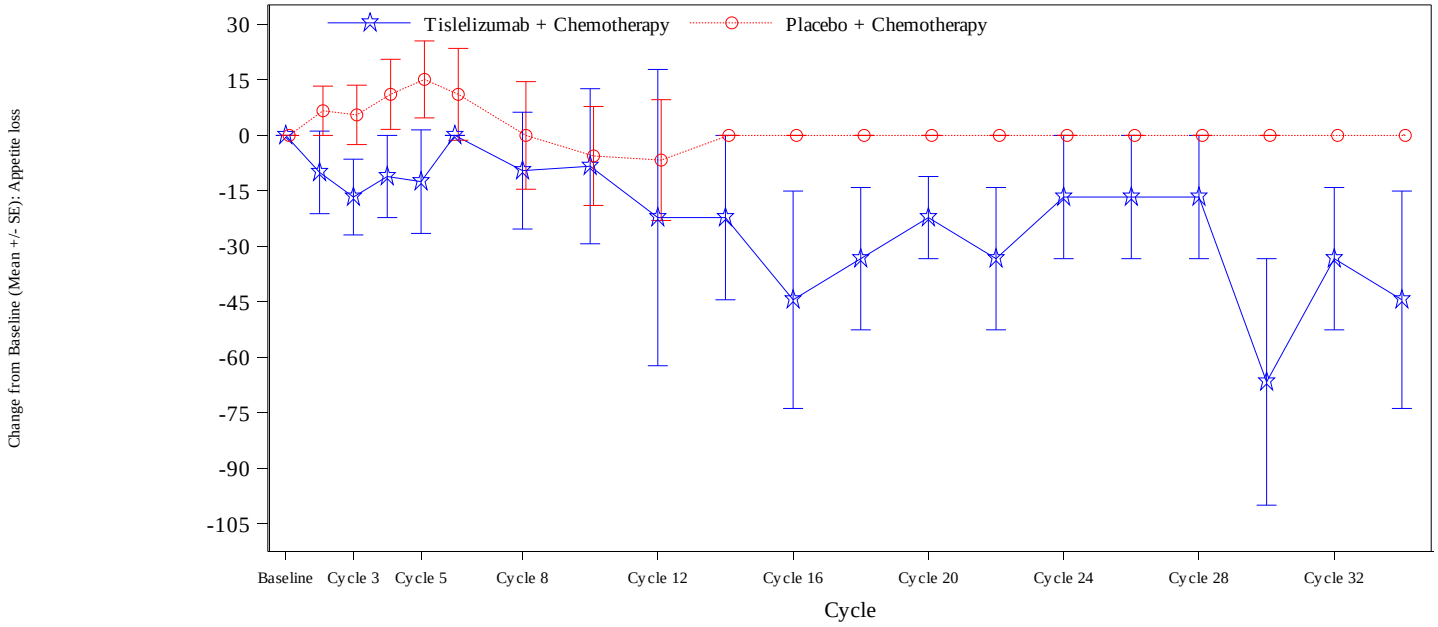

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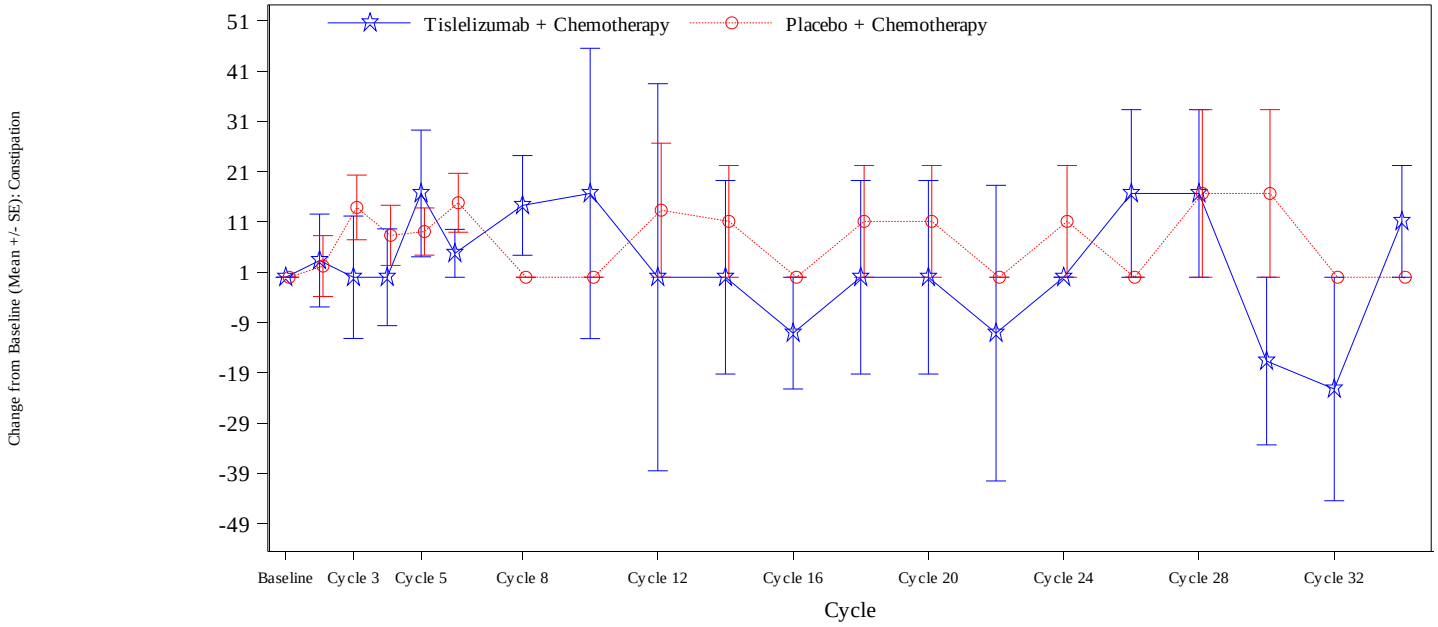

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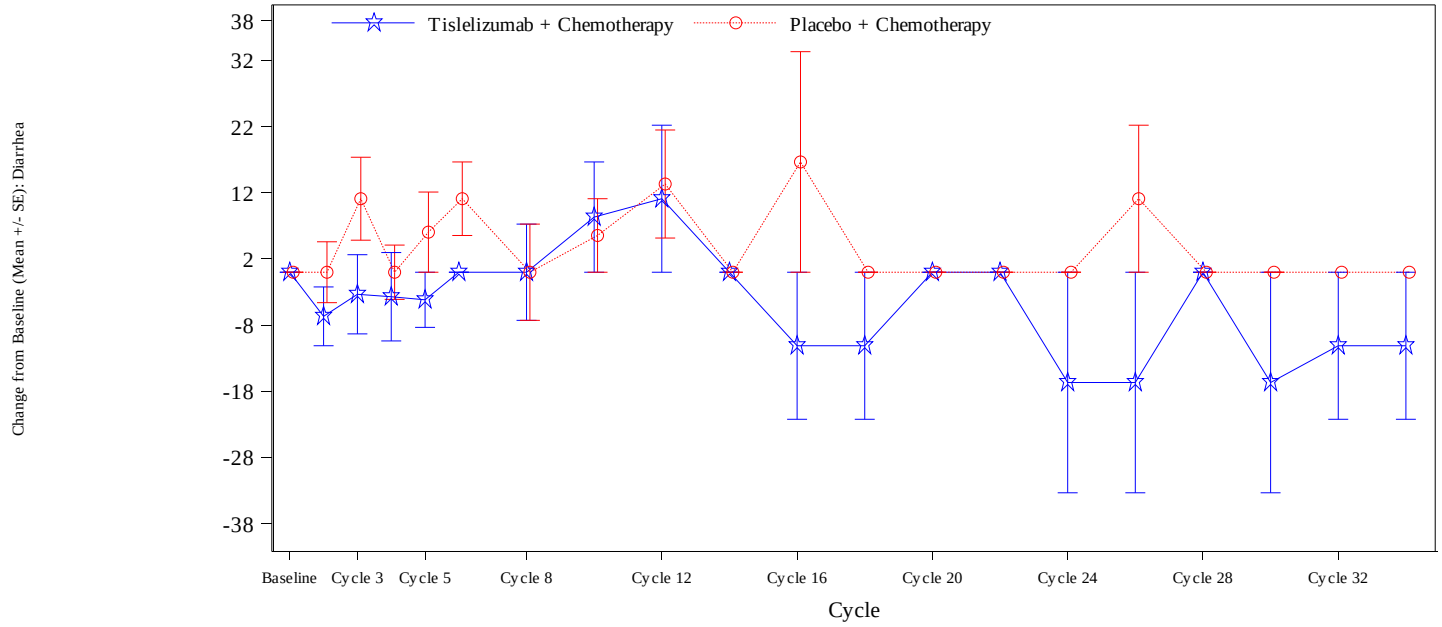

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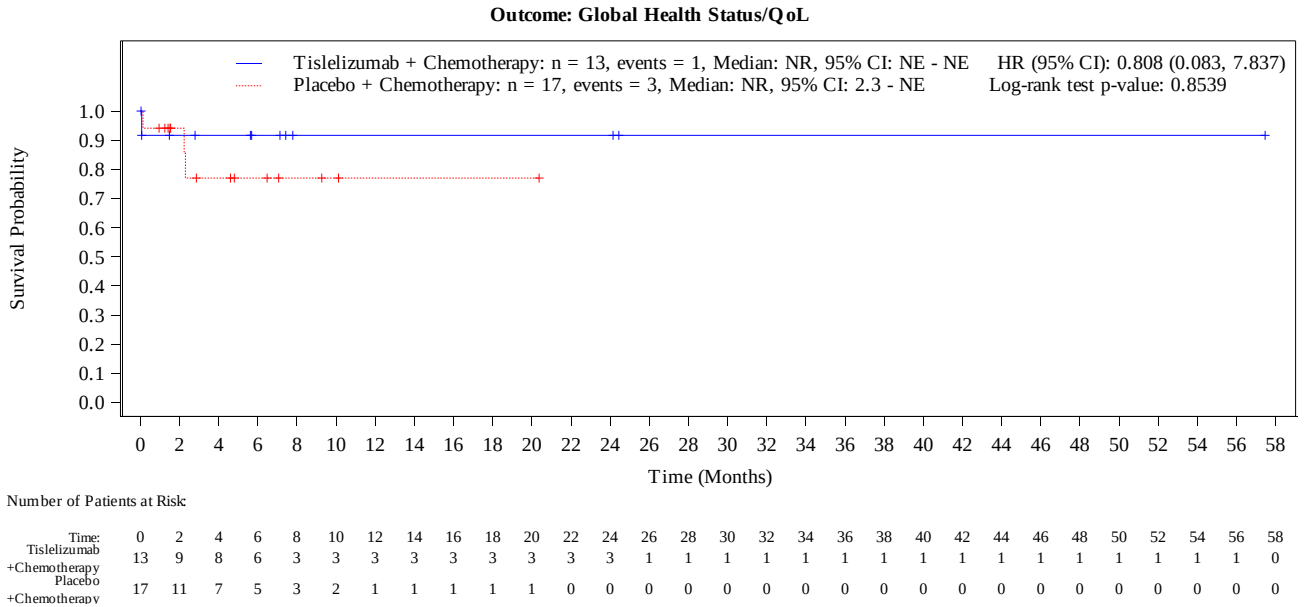
Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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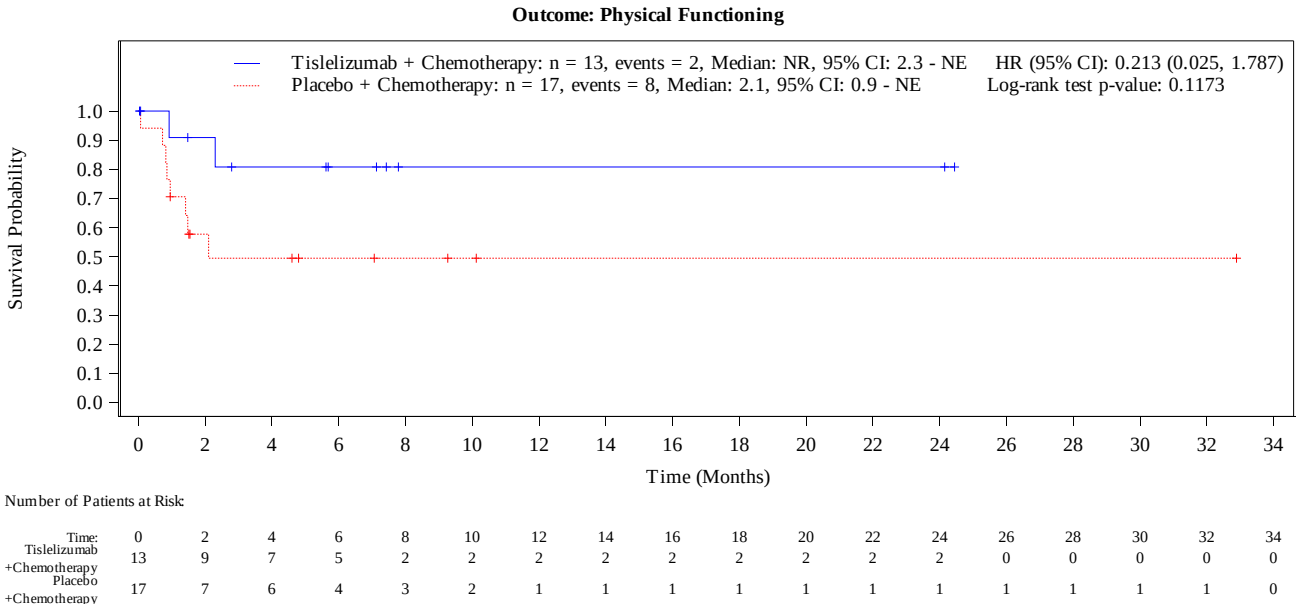

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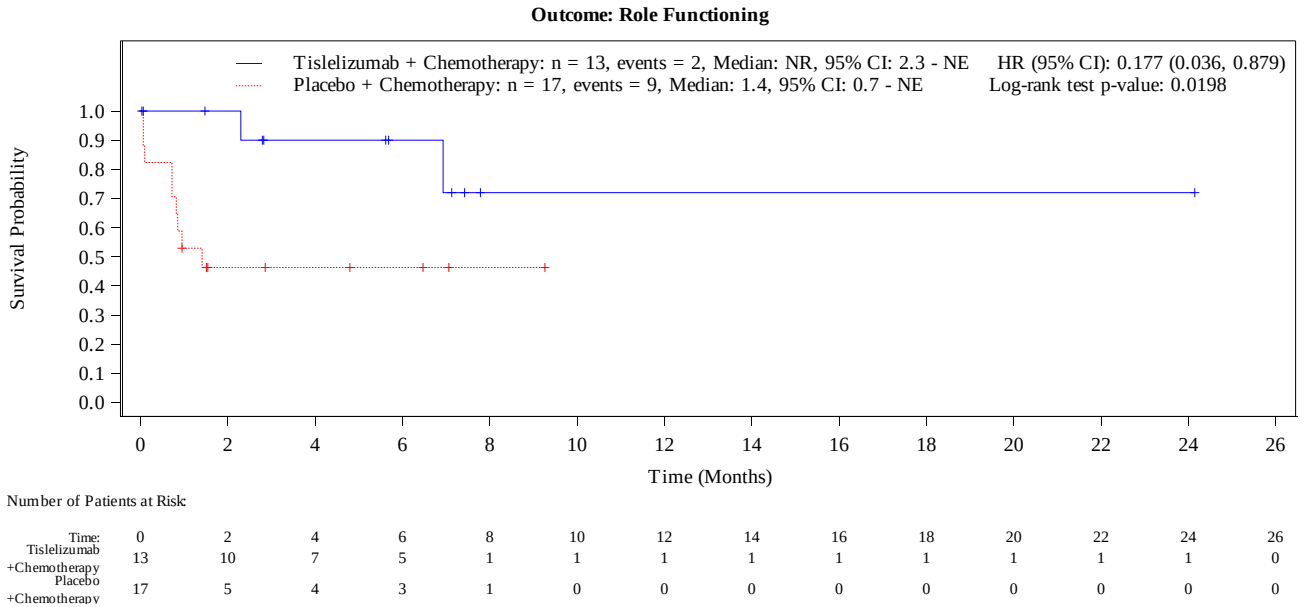

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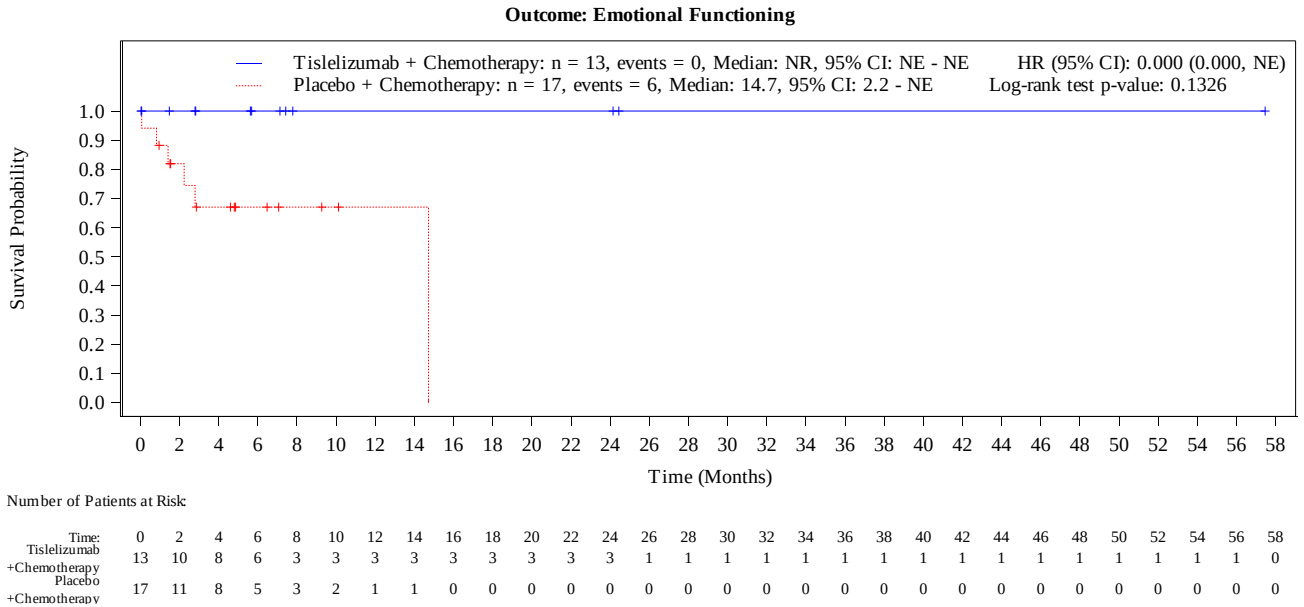

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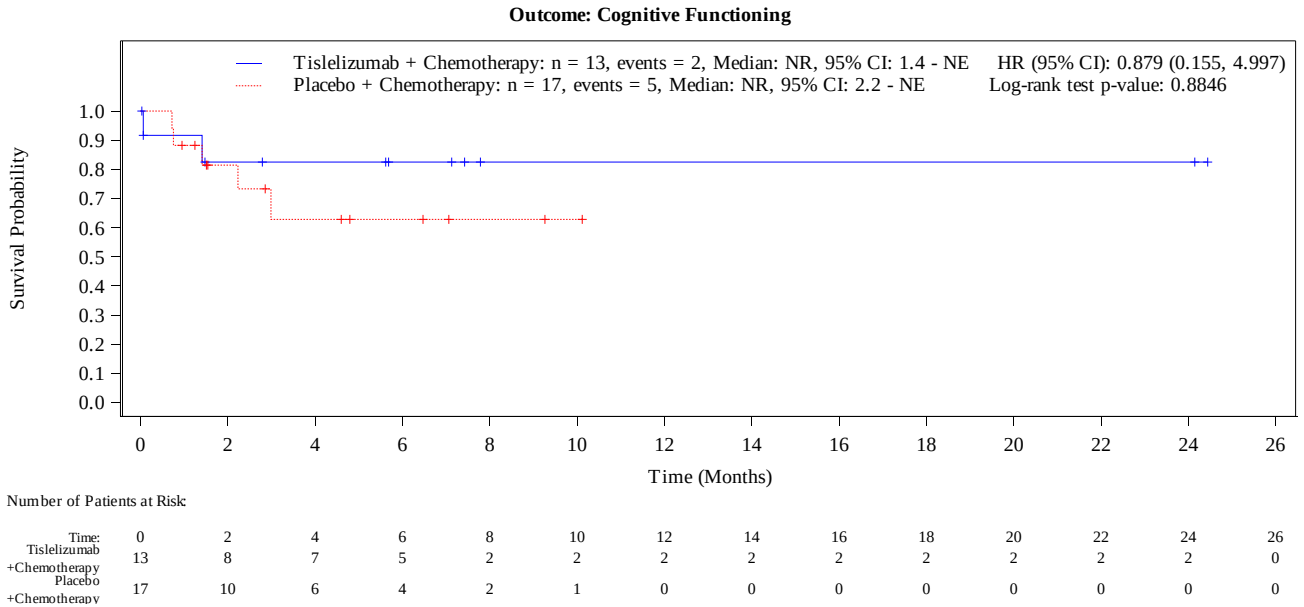

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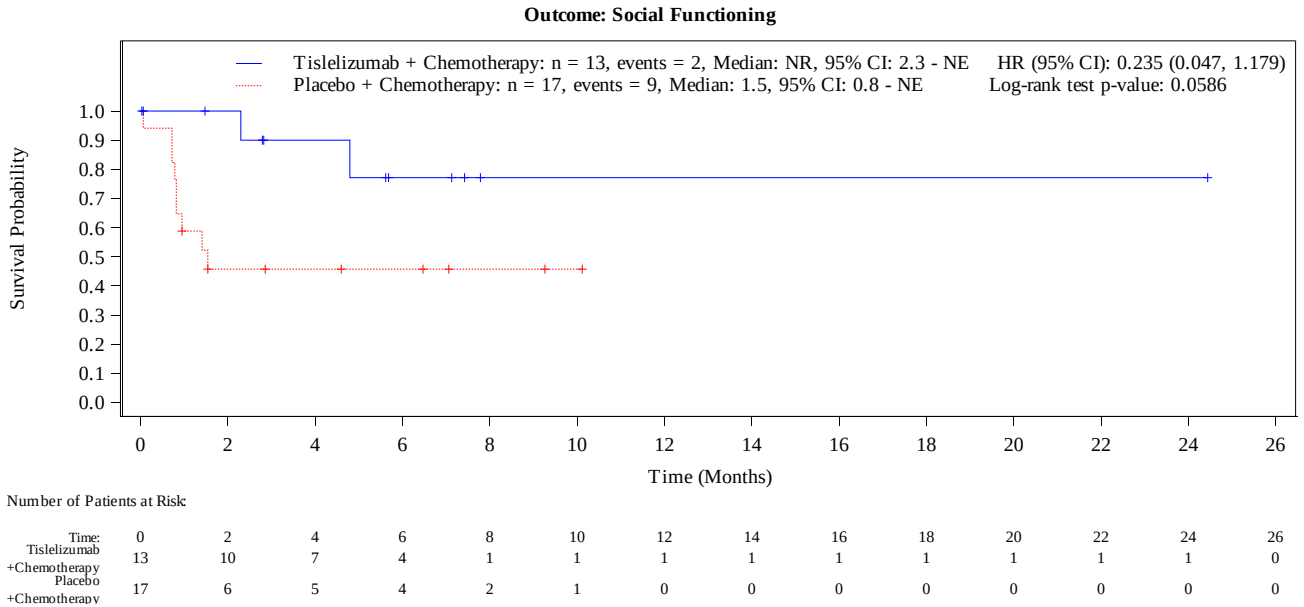

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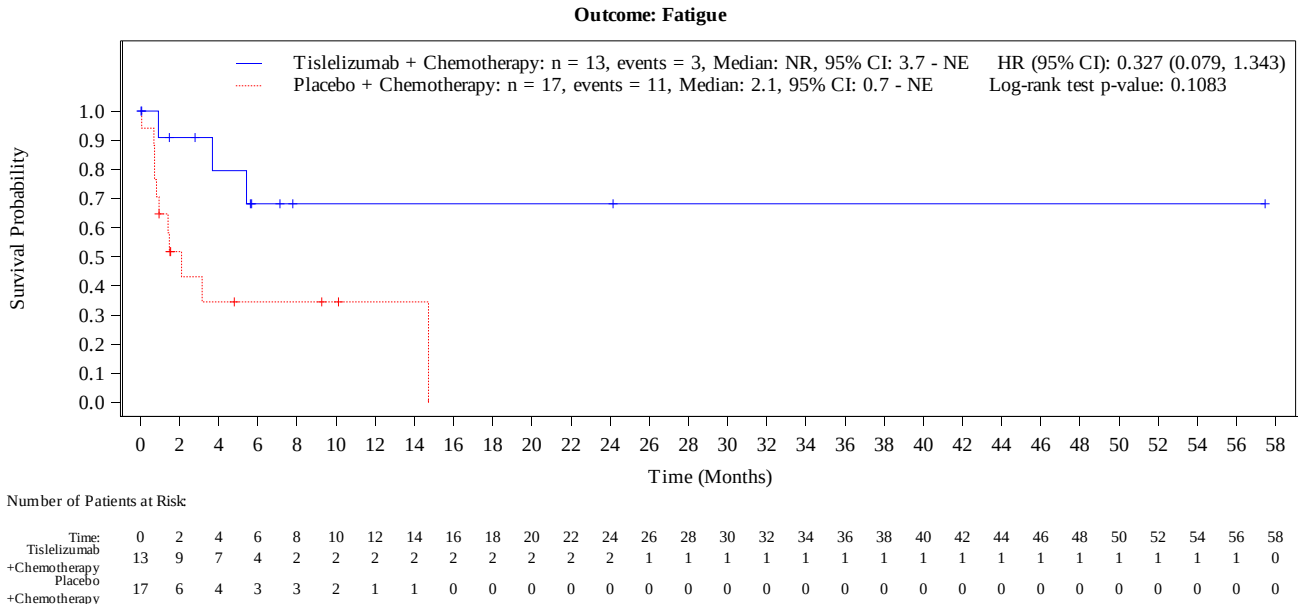

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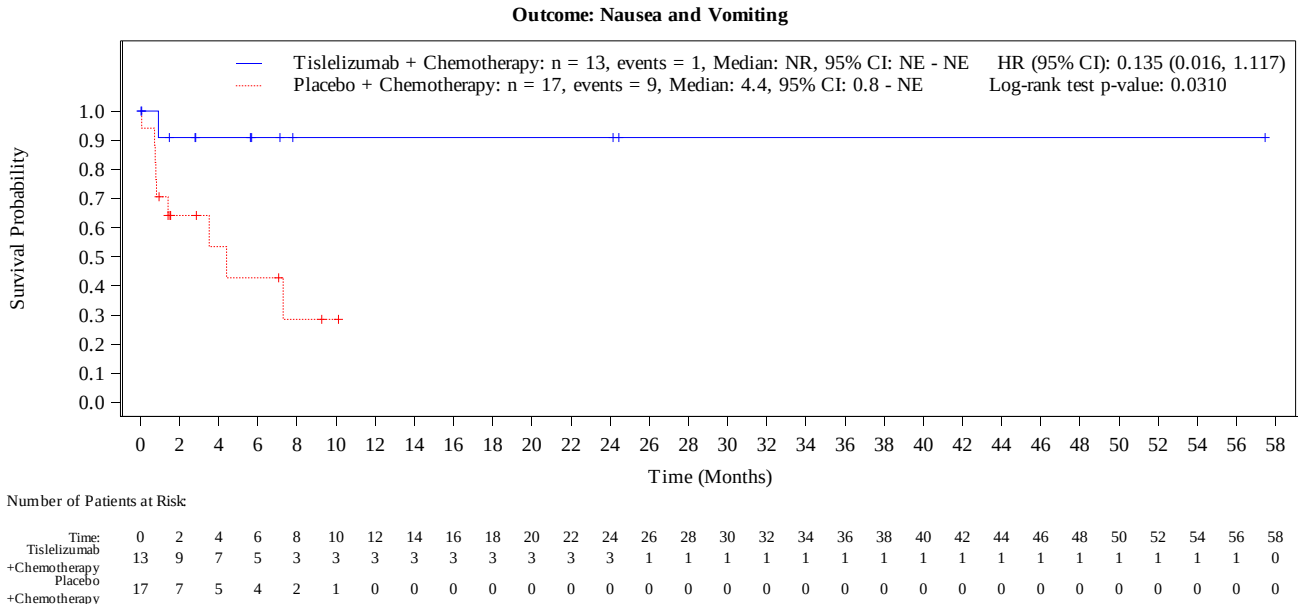

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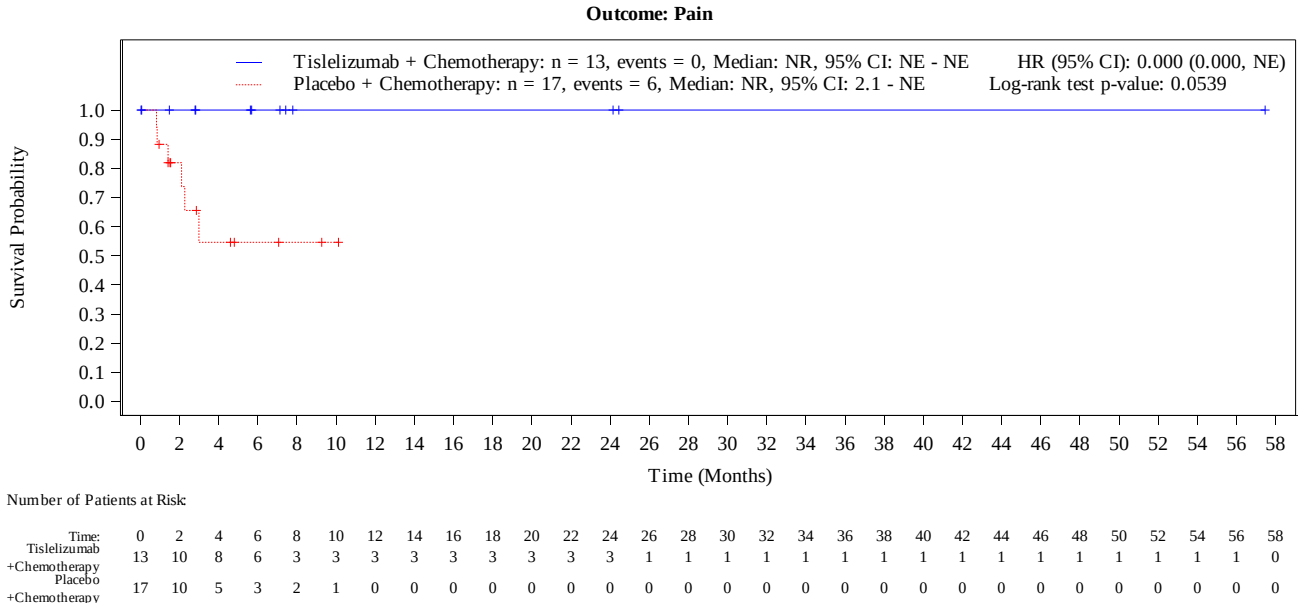

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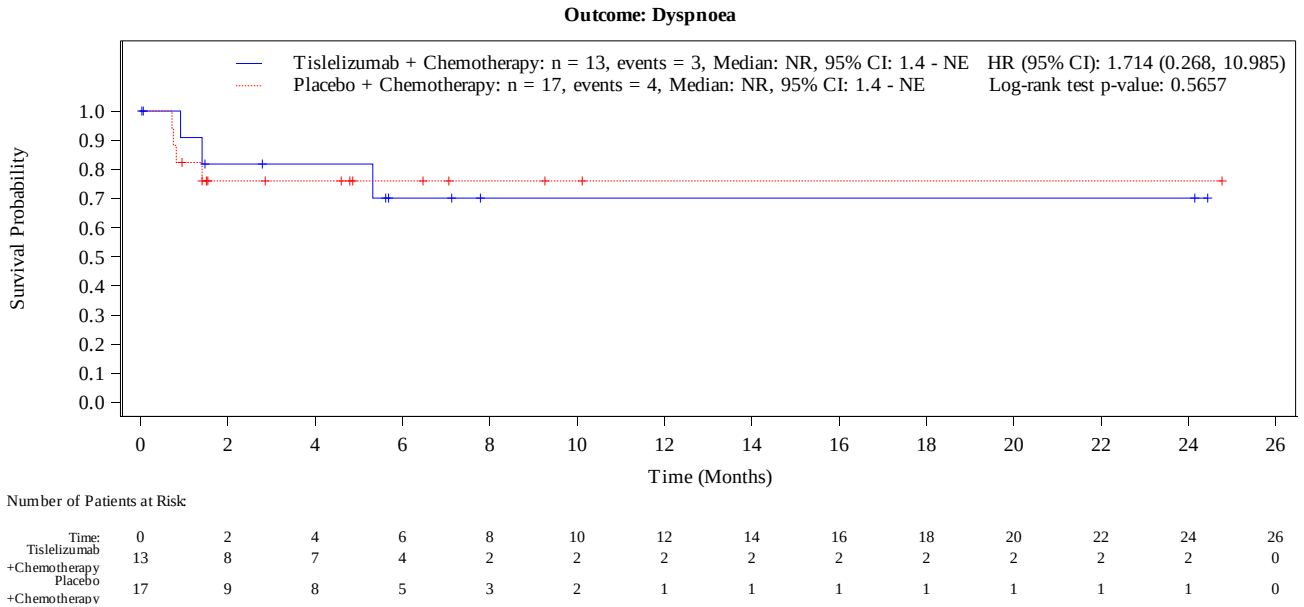

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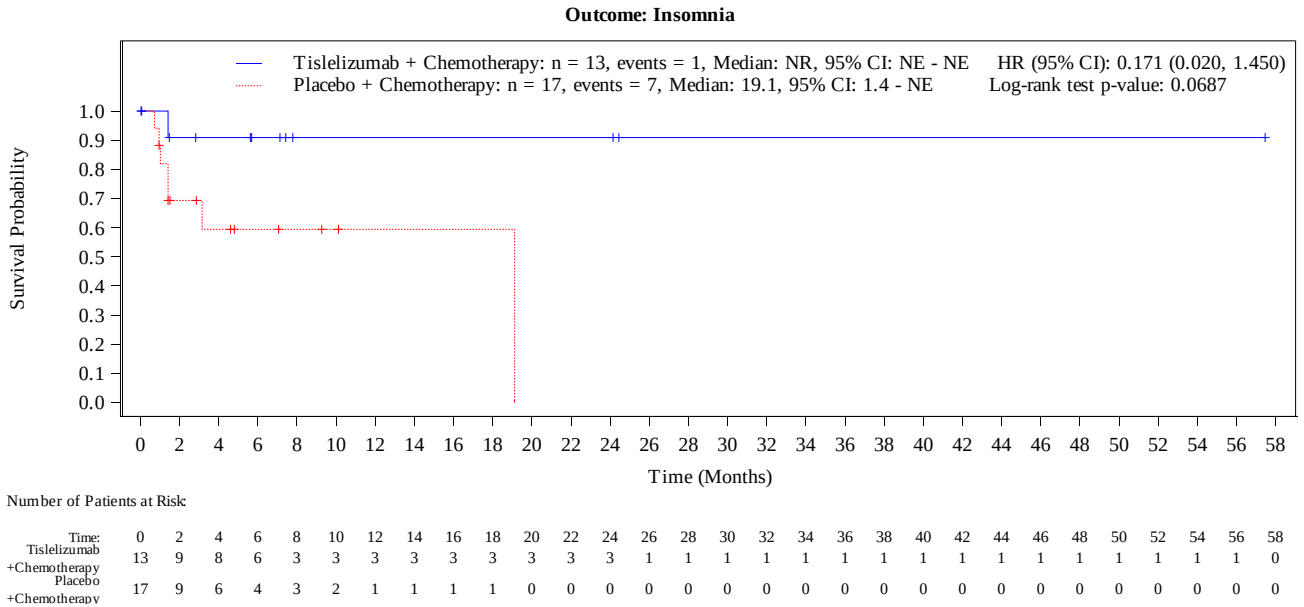

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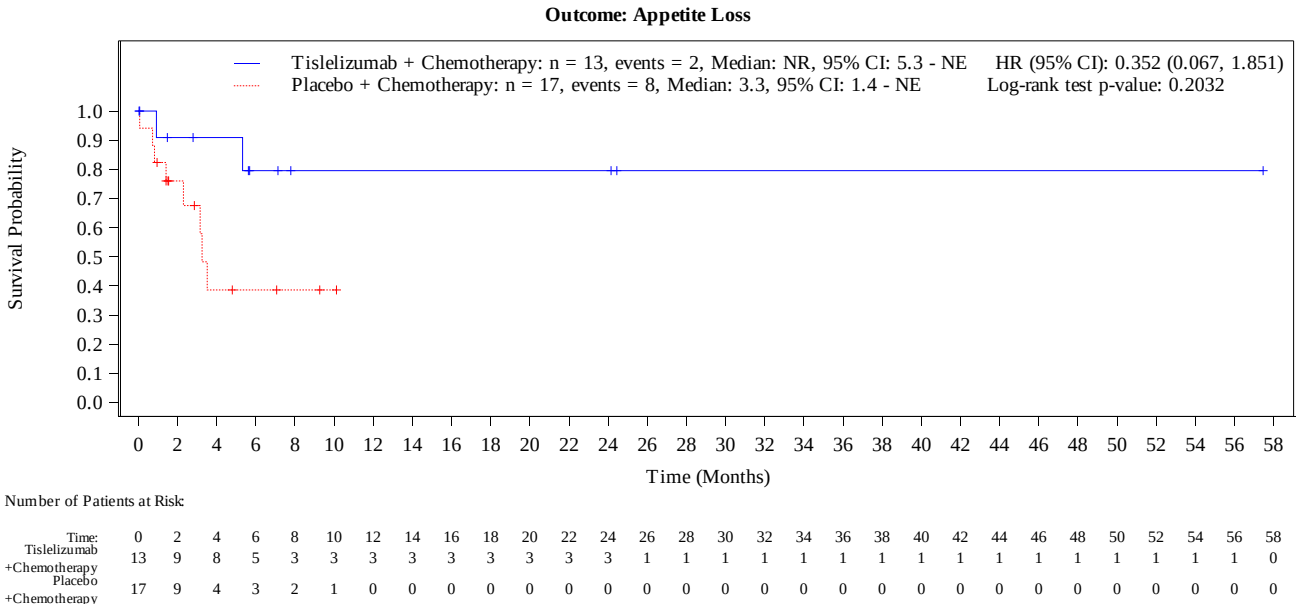
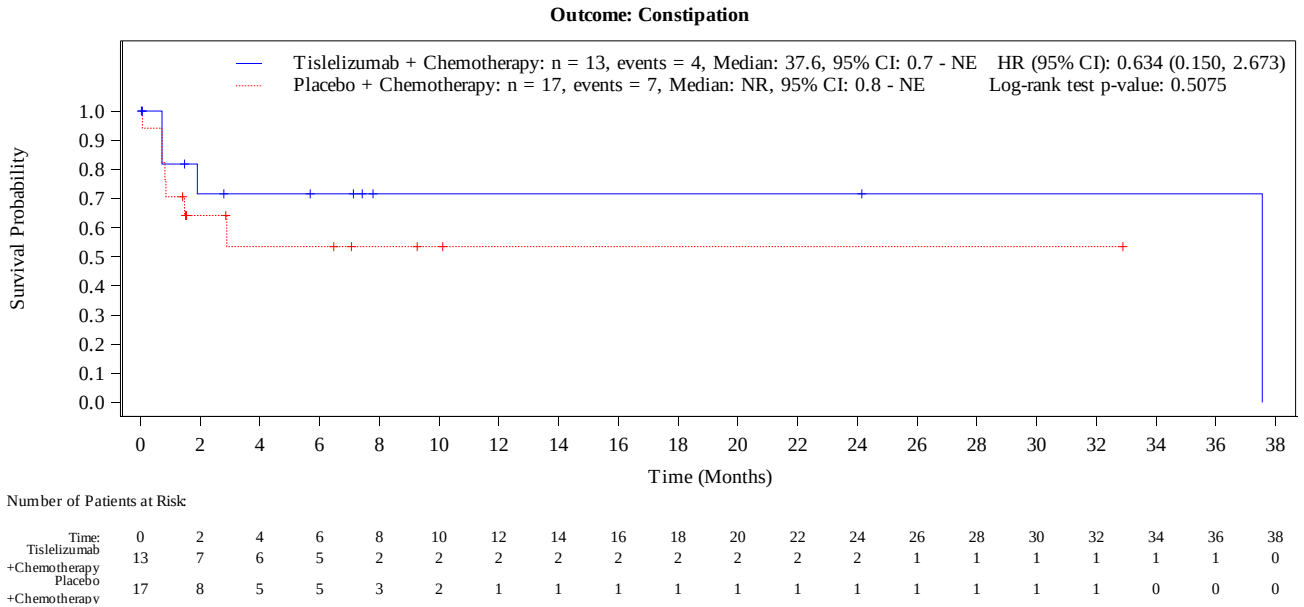
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-qs.sas 14NOV2024 05:56 f-14-2-7-1-2-km-qs-c30-pop1-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



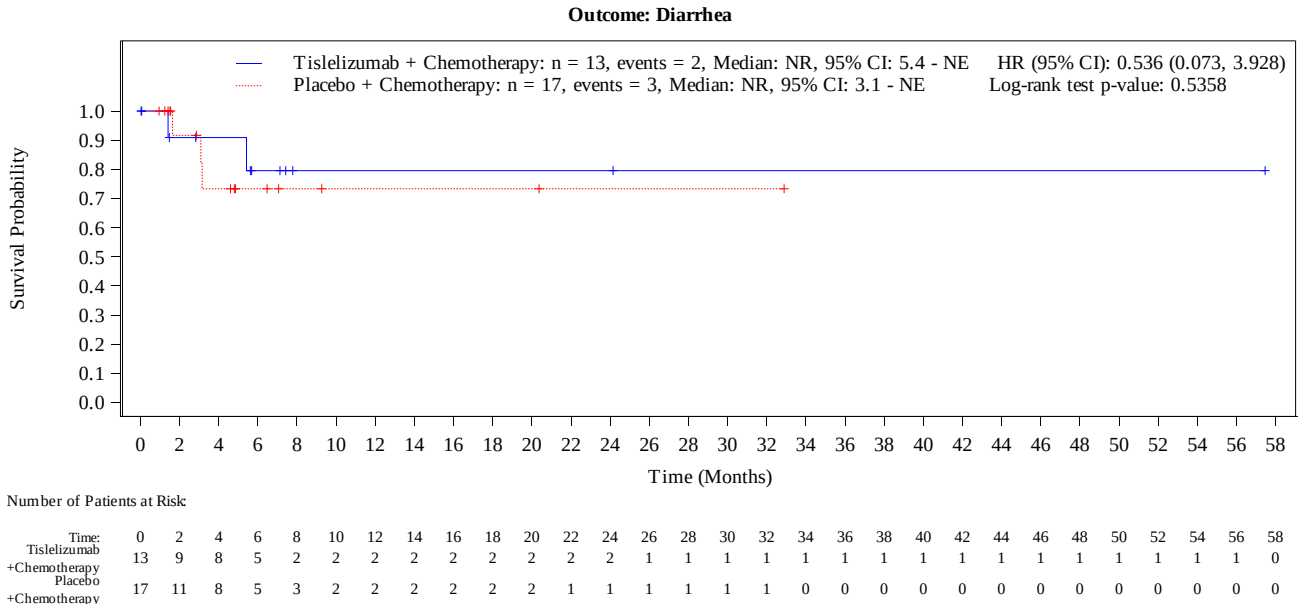
Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-qs.sas 14NOV2024 05:56 f-14-2-7-1-2-km-qs-c30-pop1-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-qs.sas 14NOV2024 05:56 f-14-2-7-1-2-km-qs-c30-pop1-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-qs.sas 14NOV2024 05:56 f-14-2-7-1-2-km-qs-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Global Health Status/QoL

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Physical Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	6 (85.7)	--	--	--
No	9	0 (0.0)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	7 (63.6)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Role Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Emotional Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	3 (37.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Cognitive Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	4 (50.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Social Functioning

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	5 (50.0)	--	--	--
1	6	2 (33.3)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	6 (75.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	7 (63.6)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Fatigue

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	6 (60.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	7 (100.0)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	5 (83.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Nausea and Vomiting

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	0 (0.0)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	2 (18.2)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dyspnoea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Insomnia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Appetite Loss

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	0 (0.0)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Constipation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	2 (33.3)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	3 (42.9)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-2-1-2-s-eff-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Diarrhea

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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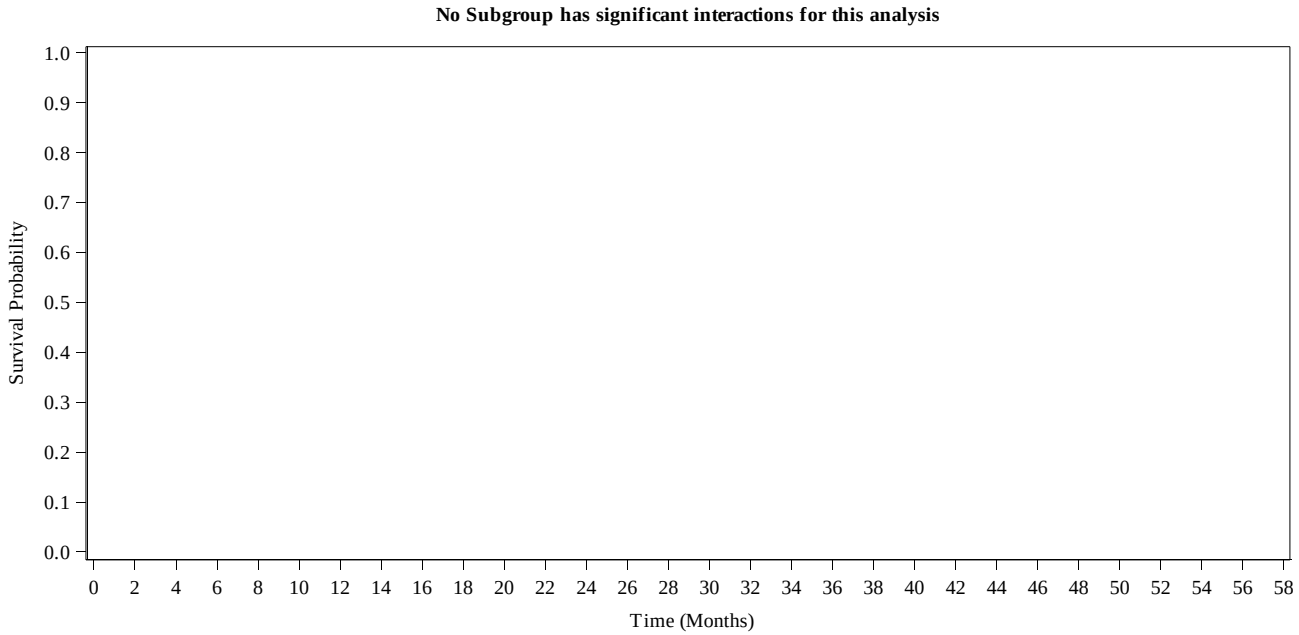
Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 14NOV2024 06:23 f-14-2-7-1-2-s-km-tteqs-subgrp-c30-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	53.7 (36.03)		58.2 (33.22)	
	Median	61.1		66.7	
	Q1, Q3	22.2, 83.3		33.3, 77.8	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	63.3 (40.25)	4.4 (19.74)	60.0 (34.32)	0.0 (34.12)
	Median	77.8	5.6	66.7	0.0
	Q1, Q3	11.1, 100.0	0.0, 11.1	33.3, 88.9	-33.3, 11.1
	Min, Max	0, 100	-33, 44	0, 100	-56, 78
Cycle 3	n	10	10	11	11
	Mean (SD)	56.7 (36.83)	-2.2 (15.54)	44.4 (39.13)	-18.2 (22.92)
	Median	66.7	0.0	55.6	-11.1
	Q1, Q3	22.2, 88.9	0.0, 0.0	0.0, 88.9	-33.3, 0.0
	Min, Max	0, 100	-33, 22	0, 100	-56, 11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	75.3 (35.91)	19.8 (33.69)	37.0 (37.41)	-20.4 (23.61)
	Median	88.9	11.1	38.9	-11.1
	Q1, Q3	66.7, 100.0	0.0, 22.2	0.0, 66.7	-33.3, 0.0
	Min, Max	0, 100	-22, 89	0, 100	-67, 0
Cycle 5	n	8	8	11	11
	Mean (SD)	62.5 (40.69)	9.7 (22.57)	49.5 (38.61)	-13.1 (26.68)
	Median	83.3	11.1	44.4	-11.1
	Q1, Q3	22.2, 94.4	0.0, 22.2	11.1, 100.0	-33.3, 0.0
	Min, Max	0, 100	-33, 44	0, 100	-67, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	66.7 (40.57)	14.3 (19.99)	54.3 (40.61)	-6.2 (31.48)
	Median	77.8	11.1	66.7	0.0
	Q1, Q3	22.2, 100.0	0.0, 22.2	11.1, 77.8	-11.1, 0.0
	Min, Max	0, 100	0, 56	0, 100	-67, 44

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	65.1 (46.00)	14.3 (46.13)	39.7 (41.00)	-15.9 (23.88)
	Median	88.9	0.0	33.3	-11.1
	Q1, Q3	0.0, 100.0	0.0, 55.6	0.0, 88.9	-22.2, 0.0
	Min, Max	0, 100	-56, 89	0, 100	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	47.2 (44.79)	-8.3 (33.18)	48.1 (45.36)	-7.4 (41.38)
	Median	44.4	0.0	44.4	0.0
	Q1, Q3	11.1, 83.3	-27.8, 11.1	0.0, 100.0	-44.4, 22.2
	Min, Max	0, 100	-56, 22	0, 100	-67, 44
Cycle 12	n	3	3	5	5
	Mean (SD)	7.4 (12.83)	-44.4 (61.86)	60.0 (43.46)	-6.7 (44.17)
	Median	0.0	-55.6	66.7	0.0
	Q1, Q3	0.0, 22.2	-100.0, 22.2	33.3, 100.0	-33.3, 22.2
	Min, Max	0, 22	-100, 22	0, 100	-67, 44

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	63.0 (54.81)	11.1 (98.76)	63.0 (54.81)	-25.9 (35.72)
	Median	88.9	44.4	88.9	-11.1
	Q1, Q3	0.0, 100.0	-100.0, 88.9	0.0, 100.0	-66.7, 0.0
	Min, Max	0, 100	-100, 89	0, 100	-67, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	37.0 (54.81)	-14.8 (75.63)	33.3 (47.14)	-22.2 (15.71)
	Median	11.1	11.1	33.3	-22.2
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-33.3, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-33, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	40.7 (44.91)	-11.1 (94.93)	22.2 (38.49)	-37.0 (27.96)
	Median	33.3	-22.2	0.0	-33.3
	Q1, Q3	0.0, 88.9	-100.0, 88.9	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 89	-100, 89	0, 67	-67, -11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	-18.5 (73.98)	22.2 (38.49)	-37.0 (27.96)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 100.0	-100.0, 44.4	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 100	-100, 44	0, 67	-67, -11
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-40.7 (52.51)	40.7 (39.02)	-18.5 (50.10)
	Median	0.0	-22.2	44.4	-22.2
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 77.8	-66.7, 33.3
	Min, Max	0, 33	-100, 0	0, 78	-67, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	-33.3 (94.28)	22.2 (38.49)	-37.0 (27.96)
	Median	16.7	-33.3	0.0	-33.3
	Q1, Q3	0.0, 33.3	-100.0, 33.3	0.0, 66.7	-66.7, -11.1
	Min, Max	0, 33	-100, 33	0, 67	-67, -11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	29.6 (42.07)	-29.6 (23.13)
	Median	0.0	-50.0	11.1	-22.2
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 77.8	-55.6, -11.1
	Min, Max	0, 0	-100, 0	0, 78	-56, -11
Cycle 28	n	2	2	2	2
	Mean (SD)	5.6 (7.86)	-44.4 (78.57)	38.9 (55.00)	-16.7 (7.86)
	Median	5.6	-44.4	38.9	-16.7
	Q1, Q3	0.0, 11.1	-100.0, 11.1	0.0, 77.8	-22.2, -11.1
	Min, Max	0, 11	-100, 11	0, 78	-22, -11
Cycle 30	n	2	2	2	2
	Mean (SD)	5.6 (7.86)	-22.2 (47.14)	33.3 (47.14)	-22.2 (15.71)
	Median	5.6	-22.2	33.3	-22.2
	Q1, Q3	0.0, 11.1	-55.6, 11.1	0.0, 66.7	-33.3, -11.1
	Min, Max	0, 11	-56, 11	0, 67	-33, -11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	3.7 (6.42)	-48.1 (55.92)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-55.6	0.0	-11.1
	Q1, Q3	0.0, 11.1	-100.0, 11.1	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 11	-100, 11	0, 0	-11, -11
Cycle 34	n	3	3	1	1
	Mean (SD)	29.6 (51.32)	-22.2 (98.76)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-55.6	0.0	-11.1
	Q1, Q3	0.0, 88.9	-100.0, 88.9	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 89	-100, 89	0, 0	-11, -11
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-100.0 (NE)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-100.0	0.0	-11.1
	Q1, Q3	0.0, 0.0	-100.0, -100.0	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 0	-100, -100	0, 0	-11, -11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-11.1 (NE)
	Median			0.0	-11.1
	Q1, Q3			0.0, 0.0	-11.1, -11.1
	Min, Max			0, 0	-11, -11
Cycle 42	n	1	1	1	1
	Mean (SD)	11.1 (NE)	-44.4 (NE)	22.2 (NE)	11.1 (NE)
	Median	11.1	-44.4	22.2	11.1
	Q1, Q3	11.1, 11.1	-44.4, -44.4	22.2, 22.2	11.1, 11.1
	Min, Max	11, 11	-44, -44	22, 22	11, 11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			22.2 (NE)	11.1 (NE)
	Median			22.2	11.1
	Q1, Q3			22.2, 22.2	11.1, 11.1
	Min, Max			22, 22	11, 11
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-55.6 (NE)	0.0 (NE)	-11.1 (NE)
	Median	0.0	-55.6	0.0	-11.1
	Q1, Q3	0.0, 0.0	-55.6, -55.6	0.0, 0.0	-11.1, -11.1
	Min, Max	0, 0	-56, -56	0, 0	-11, -11
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-55.6 (NE)		
	Median	0.0	-55.6		
	Q1, Q3	0.0, 0.0	-55.6, -55.6		
	Min, Max	0, 0	-56, -56		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	44.4 (NE)		
	Median	100.0	44.4		
	Q1, Q3	100.0, 100.0	44.4, 44.4		
	Min, Max	100, 100	44, 44		
Cycle 52	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-44.4 (NE)		
	Median	11.1	-44.4		
	Q1, Q3	11.1, 11.1	-44.4, -44.4		
	Min, Max	11, 11	-44, -44		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-55.6 (NE)		
	Median	0.0	-55.6		
	Q1, Q3	0.0, 0.0	-55.6, -55.6		
	Min, Max	0, 0	-56, -56		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-55.6 (NE)		
	Median	0.0	-55.6		
	Q1, Q3	0.0, 0.0	-55.6, -55.6		
	Min, Max	0, 0	-56, -56		
Cycle 64	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-33.3 (NE)		
	Median	22.2	-33.3		
	Q1, Q3	22.2, 22.2	-33.3, -33.3		
	Min, Max	22, 22	-33, -33		
Cycle 66	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-33.3 (NE)		
	Median	22.2	-33.3		
	Q1, Q3	22.2, 22.2	-33.3, -33.3		
	Min, Max	22, 22	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-44.4 (NE)		
	Median	11.1	-44.4		
	Q1, Q3	11.1, 11.1	-44.4, -44.4		
	Min, Max	11, 11	-44, -44		
Cycle 70	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-33.3 (NE)		
	Median	22.2	-33.3		
	Q1, Q3	22.2, 22.2	-33.3, -33.3		
	Min, Max	22, 22	-33, -33		
Cycle 72	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-44.4 (NE)		
	Median	11.1	-44.4		
	Q1, Q3	11.1, 11.1	-44.4, -44.4		
	Min, Max	11, 11	-44, -44		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dysphagia

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	47.8 (42.89)	-1.1 (25.36)	52.1 (34.12)	-5.6 (34.43)
	Median	61.1	0.0	66.7	0.0
	Q1, Q3	0.0, 88.9	-11.1, 0.0	22.2, 77.8	-27.8, 11.1
	Min, Max	0, 100	-56, 44	0, 100	-56, 78
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	75.9 (38.73)	22.2 (31.43)	82.4 (19.66)	24.2 (27.00)
	Median	94.4	16.7	88.9	22.2
	Q1, Q3	66.7, 100.0	0.0, 33.3	77.8, 100.0	11.1, 33.3
	Min, Max	0, 100	-11, 100	33, 100	-22, 78

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	27.1 (30.18)		29.4 (24.32)	
	Median	25.0		16.7	
	Q1, Q3	0.0, 33.3		8.3, 41.7	
	Min, Max	0, 100		0, 75	
Cycle 2	n	10	10	15	15
	Mean (SD)	15.0 (17.92)	-10.8 (32.64)	35.6 (26.81)	6.1 (16.20)
	Median	8.3	0.0	33.3	0.0
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 41.7	-8.3, 16.7
	Min, Max	0, 50	-100, 17	0, 100	-17, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	15.0 (16.57)	-10.8 (31.93)	32.6 (26.99)	-0.8 (18.80)
	Median	12.5	0.0	25.0	0.0
	Q1, Q3	0.0, 25.0	0.0, 0.0	16.7, 50.0	-8.3, 16.7
	Min, Max	0, 42	-100, 8	0, 92	-42, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	9.3 (12.11)	-15.7 (33.71)	34.7 (25.58)	4.2 (18.97)
	Median	8.3	0.0	25.0	0.0
	Q1, Q3	0.0, 8.3	-16.7, 0.0	16.7, 58.3	-4.2, 12.5
	Min, Max	0, 33	-100, 8	0, 75	-25, 50
Cycle 5	n	8	8	11	11
	Mean (SD)	10.4 (10.68)	-14.6 (32.35)	31.8 (29.06)	5.3 (26.42)
	Median	8.3	0.0	25.0	8.3
	Q1, Q3	0.0, 20.8	-16.7, 0.0	0.0, 66.7	-16.7, 25.0
	Min, Max	0, 25	-92, 8	0, 67	-42, 50
Cycle 6	n	7	7	9	9
	Mean (SD)	13.1 (16.57)	-1.2 (7.50)	25.9 (23.73)	0.0 (22.44)
	Median	0.0	0.0	25.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	8.3, 33.3	-8.3, 16.7
	Min, Max	0, 33	-17, 8	0, 67	-42, 25

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	-17.9 (37.40)	21.4 (24.47)	3.6 (27.58)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 50.0	-16.7, 25.0
	Min, Max	0, 33	-100, 8	0, 58	-42, 42
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (15.96)	-18.8 (43.23)	19.4 (36.77)	0.0 (34.56)
	Median	25.0	0.0	0.0	-8.3
	Q1, Q3	8.3, 33.3	-41.7, 4.2	0.0, 25.0	-16.7, 16.7
	Min, Max	0, 33	-83, 8	0, 92	-42, 58
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-33.3 (57.74)	16.7 (28.26)	-6.7 (27.26)
	Median	0.0	0.0	8.3	-8.3
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 8.3	-16.7, 0.0
	Min, Max	0, 33	-100, 0	0, 67	-42, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	2.8 (4.81)	-41.7 (46.40)	16.7 (22.05)	-5.6 (12.73)
	Median	0.0	-33.3	8.3	-8.3
	Q1, Q3	0.0, 8.3	-91.7, 0.0	0.0, 41.7	-16.7, 8.3
	Min, Max	0, 8	-92, 0	0, 42	-17, 8
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-38.9 (41.94)	20.8 (29.46)	0.0 (11.79)
	Median	0.0	-33.3	20.8	0.0
	Q1, Q3	0.0, 16.7	-83.3, 0.0	0.0, 41.7	-8.3, 8.3
	Min, Max	0, 17	-83, 0	0, 42	-8, 8
Cycle 18	n	3	3	3	3
	Mean (SD)	19.4 (17.35)	-25.0 (43.30)	16.7 (16.67)	-2.8 (12.73)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	-75.0, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-75, 0	0, 33	-17, 8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	16.7 (16.67)	-2.8 (12.73)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 8.3
	Min, Max	0, 33	-67, 0	0, 33	-17, 8
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-33.3 (33.33)	22.2 (19.25)	2.8 (20.97)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 33.3	-16.7, 25.0
	Min, Max	0, 33	-67, 0	0, 33	-17, 25
Cycle 24	n	2	2	3	3
	Mean (SD)	8.3 (11.79)	-8.3 (11.79)	19.4 (12.73)	0.0 (8.33)
	Median	8.3	-8.3	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	8.3, 33.3	-8.3, 8.3
	Min, Max	0, 17	-17, 0	8, 33	-8, 8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	12.5 (17.68)	-4.2 (5.89)	22.2 (9.62)	2.8 (4.81)
	Median	12.5	-4.2	16.7	0.0
	Q1, Q3	0.0, 25.0	-8.3, 0.0	16.7, 33.3	0.0, 8.3
	Min, Max	0, 25	-8, 0	17, 33	0, 8
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	29.2 (5.89)	8.3 (11.79)
	Median	16.7	0.0	29.2	8.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	25.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 0	25, 33	0, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-50.0 (70.71)	20.8 (29.46)	0.0 (11.79)
	Median	16.7	-50.0	20.8	0.0
	Q1, Q3	0.0, 33.3	-100.0, 0.0	0.0, 41.7	-8.3, 8.3
	Min, Max	0, 33	-100, 0	0, 42	-8, 8

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	19.4 (17.35)	-25.0 (43.30)	8.3 (NE)	0.0 (NE)
	Median	25.0	0.0	8.3	0.0
	Q1, Q3	0.0, 33.3	-75.0, 0.0	8.3, 8.3	0.0, 0.0
	Min, Max	0, 33	-75, 0	8, 8	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	8.3 (14.43)	-36.1 (37.58)	16.7 (NE)	8.3 (NE)
	Median	0.0	-33.3	16.7	8.3
	Q1, Q3	0.0, 25.0	-75.0, 0.0	16.7, 16.7	8.3, 8.3
	Min, Max	0, 25	-75, 0	17, 17	8, 8
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	8.3 (NE)	0.0 (NE)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	8.3, 8.3	0.0, 0.0
	Min, Max	0, 0	0, 0	8, 8	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

Visit		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
		Observed	Change from Baseline	Observed	Change from Baseline
Cycle 38	n	0	0	1	1
	Mean (SD)			8.3 (NE)	0.0 (NE)
	Median			8.3	0.0
	Q1, Q3			8.3, 8.3	0.0, 0.0
	Min, Max			8, 8	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			16.7 (NE)	8.3 (NE)
	Median			16.7	8.3
	Q1, Q3			16.7, 16.7	8.3, 8.3
	Min, Max			17, 17	8, 8
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	-66.7 (NE)	8.3 (NE)	0.0 (NE)
	Median	33.3	-66.7	8.3	0.0
	Q1, Q3	33.3, 33.3	-66.7, -66.7	8.3, 8.3	0.0, 0.0
	Min, Max	33, 33	-67, -67	8, 8	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

Visit		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
		Observed	Change from Baseline	Observed	Change from Baseline
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	25.0 (NE)
	Median			33.3	25.0
	Q1, Q3			33.3, 33.3	25.0, 25.0
	Min, Max			33, 33	25, 25
Cycle 46	n	1	1	1	1
	Mean (SD)	41.7 (NE)	-58.3 (NE)	25.0 (NE)	16.7 (NE)
	Median	41.7	-58.3	25.0	16.7
	Q1, Q3	41.7, 41.7	-58.3, -58.3	25.0, 25.0	16.7, 16.7
	Min, Max	42, 42	-58, -58	25, 25	17, 17
Cycle 48	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	58.3 (NE)	-41.7 (NE)		
	Median	58.3	-41.7		
	Q1, Q3	58.3, 58.3	-41.7, -41.7		
	Min, Max	58, 58	-42, -42		
Cycle 52	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		
Cycle 56	n	1	1	0	0
	Mean (SD)	25.0 (NE)	-75.0 (NE)		
	Median	25.0	-75.0		
	Q1, Q3	25.0, 25.0	-75.0, -75.0		
	Min, Max	25, 25	-75, -75		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	83.3 (NE)	-16.7 (NE)		
	Median	83.3	-16.7		
	Q1, Q3	83.3, 83.3	-16.7, -16.7		
	Min, Max	83, 83	-17, -17		
Cycle 64	n	1	1	0	0
	Mean (SD)	41.7 (NE)	-58.3 (NE)		
	Median	41.7	-58.3		
	Q1, Q3	41.7, 41.7	-58.3, -58.3		
	Min, Max	42, 42	-58, -58		
Cycle 66	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	50.0 (NE)	-50.0 (NE)		
	Median	50.0	-50.0		
	Q1, Q3	50.0, 50.0	-50.0, -50.0		
	Min, Max	50, 50	-50, -50		
Cycle 70	n	1	1	0	0
	Mean (SD)	41.7 (NE)	-58.3 (NE)		
	Median	41.7	-58.3		
	Q1, Q3	41.7, 41.7	-58.3, -58.3		
	Min, Max	42, 42	-58, -58		
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Eating

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	20.0 (18.09)	-5.8 (21.89)	39.6 (27.47)	9.4 (25.07)
	Median	20.8	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-16.7, 8.3	16.7, 58.3	0.0, 29.2
	Min, Max	0, 50	-50, 17	0, 83	-42, 58
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	36.1 (30.01)	9.0 (13.51)	56.4 (25.94)	27.0 (20.10)
	Median	33.3	8.3	50.0	25.0
	Q1, Q3	8.3, 58.3	0.0, 16.7	41.7, 66.7	16.7, 41.7
	Min, Max	0, 83	-17, 33	17, 100	-8, 58

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	4.2 (10.36)		12.7 (20.01)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 16.7	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	1.7 (5.27)	-3.3 (10.54)	14.4 (17.67)	3.3 (9.34)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 17	-33, 0	0, 50	-17, 17
Cycle 3	n	10	10	11	11
	Mean (SD)	5.0 (11.25)	0.0 (7.86)	18.2 (17.41)	4.5 (16.82)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-17, 17	0, 50	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	0.0 (0.00)	-5.6 (11.79)	13.9 (18.58)	1.4 (16.60)
	Median	0.0	0.0	8.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 8.3
	Min, Max	0, 0	-33, 0	0, 50	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	2.1 (5.89)	-4.2 (7.72)	13.6 (17.98)	1.5 (17.41)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-8.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	0, 50	-33, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	0.0 (0.00)	16.7 (16.67)	1.9 (22.74)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 50	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	7.1 (13.11)	0.0 (0.00)	9.5 (16.27)	0.0 (21.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 33	0, 0	0, 33	-33, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	20.8 (20.97)	8.3 (9.62)	5.6 (13.61)	-5.6 (17.21)
	Median	16.7	8.3	0.0	0.0
	Q1, Q3	8.3, 33.3	0.0, 16.7	0.0, 0.0	-16.7, 0.0
	Min, Max	0, 50	0, 17	0, 33	-33, 17
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	6.7 (9.13)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	5.6 (9.62)	0.0 (0.00)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	5.6 (9.62)	-11.1 (9.62)	25.0 (11.79)	8.3 (11.79)
	Median	0.0	-16.7	25.0	8.3
	Q1, Q3	0.0, 16.7	-16.7, 0.0	16.7, 33.3	0.0, 16.7
	Min, Max	0, 17	-17, 0	17, 33	0, 17
Cycle 18	n	3	3	3	3
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	22.2 (19.25)	11.1 (9.62)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 0	0, 33	0, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-5.6 (9.62)	5.6 (9.62)	-5.6 (9.62)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 0.0	0.0, 16.7	-16.7, 0.0
	Min, Max	0, 33	-17, 0	0, 17	-17, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (9.62)	-5.6 (9.62)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	-16.7, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 17	-17, 0	0, 17	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	11.1 (9.62)	0.0 (0.00)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 16.7	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 17	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	0.0 (16.67)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 0	-33, 0	0, 33	-17, 17
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	16.7 (23.57)	0.0 (23.57)
	Median	0.0	-16.7	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	0, 0	-33, 0	0, 33	-17, 17
Cycle 30	n	2	2	2	2
	Mean (SD)	25.0 (11.79)	0.0 (0.00)	16.7 (23.57)	0.0 (23.57)
	Median	25.0	0.0	16.7	0.0
	Q1, Q3	16.7, 33.3	0.0, 0.0	0.0, 33.3	-16.7, 16.7
	Min, Max	17, 33	0, 0	0, 33	-17, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	0.0 (NE)	-16.7 (NE)
	Median	16.7	0.0	0.0	-16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	0, 33	0, 0	0, 0	-17, -17
Cycle 34	n	3	3	1	1
	Mean (SD)	16.7 (16.67)	0.0 (0.00)	16.7 (NE)	0.0 (NE)
	Median	16.7	0.0	16.7	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	16.7, 16.7	0.0, 0.0
	Min, Max	0, 33	0, 0	17, 17	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	-16.7 (NE)
	Median	0.0	0.0	0.0	-16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	-16.7, -16.7
	Min, Max	0, 0	0, 0	0, 0	-17, -17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	16.7 (NE)
	Median			33.3	16.7
	Q1, Q3			33.3, 33.3	16.7, 16.7
	Min, Max			33, 33	17, 17
Cycle 42	n	1	1	1	1
	Mean (SD)	16.7 (NE)	0.0 (NE)	33.3 (NE)	16.7 (NE)
	Median	16.7	0.0	33.3	16.7
	Q1, Q3	16.7, 16.7	0.0, 0.0	33.3, 33.3	16.7, 16.7
	Min, Max	17, 17	0, 0	33, 33	17, 17

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			16.7 (NE)	0.0 (NE)
	Median			16.7	0.0
	Q1, Q3			16.7, 16.7	0.0, 0.0
	Min, Max			17, 17	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	33.3 (NE)	16.7 (NE)	0.0 (NE)	-16.7 (NE)
	Median	33.3	16.7	0.0	-16.7
	Q1, Q3	33.3, 33.3	16.7, 16.7	0.0, 0.0	-16.7, -16.7
	Min, Max	33, 33	17, 17	0, 0	-17, -17
Cycle 48	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-16.7 (NE)		
	Median	0.0	-16.7		
	Q1, Q3	0.0, 0.0	-16.7, -16.7		
	Min, Max	0, 0	-17, -17		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	66.7 (NE)	50.0 (NE)		
	Median	66.7	50.0		
	Q1, Q3	66.7, 66.7	50.0, 50.0		
	Min, Max	67, 67	50, 50		
Cycle 64	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	16.7 (NE)		
	Median	33.3	16.7		
	Q1, Q3	33.3, 33.3	16.7, 16.7		
	Min, Max	33, 33	17, 17		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
Cycle 70	n	1	1	0	0
	Mean (SD)	16.7 (NE)	0.0 (NE)		
	Median	16.7	0.0		
	Q1, Q3	16.7, 16.7	0.0, 0.0		
	Min, Max	17, 17	0, 0		
Cycle 72	n	1	1	0	0
	Mean (SD)	66.7 (NE)	50.0 (NE)		
	Median	66.7	50.0		
	Q1, Q3	66.7, 66.7	50.0, 50.0		
	Min, Max	67, 67	50, 50		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Reflux

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	10.0 (16.10)	5.0 (17.66)	16.7 (16.10)	3.1 (19.45)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 33.3	-8.3, 16.7
	Min, Max	0, 50	-33, 33	0, 33	-33, 33
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	16.7 (22.47)	12.5 (16.09)	28.4 (18.41)	15.7 (16.11)
	Median	8.3	8.3	33.3	16.7
	Q1, Q3	0.0, 25.0	0.0, 16.7	16.7, 50.0	0.0, 33.3
	Min, Max	0, 67	0, 50	0, 50	-17, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	12.0 (18.02)		22.9 (20.21)	
	Median	0.0		22.2	
	Q1, Q3	0.0, 22.2		11.1, 33.3	
	Min, Max	0, 56		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.5 (21.61)	-1.5 (15.64)
	Median	0.0	0.0	22.2	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 22	-33, 11	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	5.6 (9.44)	-6.7 (15.00)	21.2 (23.55)	-4.0 (15.13)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 33.3	-11.1, 0.0
	Min, Max	0, 22	-33, 11	0, 67	-33, 22

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (7.86)	-9.9 (15.16)	14.8 (18.55)	-8.3 (15.08)
	Median	0.0	0.0	5.6	-5.6
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 27.8	-16.7, 0.0
	Min, Max	0, 22	-33, 0	0, 56	-33, 11
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	-8.3 (12.94)	17.2 (25.99)	-3.0 (20.54)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 22.2	-22.2, 0.0
	Min, Max	0, 0	-33, 0	0, 89	-33, 44
Cycle 6	n	7	7	9	9
	Mean (SD)	1.6 (4.20)	-3.2 (10.57)	16.0 (21.60)	-2.5 (17.37)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 0.0	-11.1, 0.0	0.0, 11.1	-11.1, 11.1
	Min, Max	0, 11	-22, 11	0, 67	-33, 22

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (8.74)	-4.8 (10.84)	7.9 (12.36)	-4.8 (14.14)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 11.1	-11.1, 0.0	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (10.64)	-5.6 (14.34)	7.4 (13.46)	-5.6 (15.32)
	Median	5.6	-5.6	0.0	0.0
	Q1, Q3	0.0, 16.7	-16.7, 5.6	0.0, 11.1	-11.1, 0.0
	Min, Max	0, 22	-22, 11	0, 33	-33, 11
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (11.11)	-7.4 (12.83)	6.7 (14.91)	-8.9 (14.49)
	Median	11.1	0.0	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, 0.0	0.0, 0.0	-11.1, 0.0
	Min, Max	0, 22	-22, 0	0, 33	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	14.8 (16.97)	0.0 (11.11)
	Median	0.0	-22.2	11.1	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-11.1, 11.1
	Min, Max	0, 0	-33, 0	0, 33	-11, 11
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-22.2	16.7	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	3.7 (6.42)	-14.8 (12.83)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 11	-22, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-18.5 (16.97)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	3.7 (27.96)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-22.2, 33.3	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-22, 33	0, 33	0, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	14.8 (16.97)	3.7 (6.42)
	Median	0.0	-11.1	11.1	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 11.1
	Min, Max	0, 0	-22, 0	0, 33	0, 11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-11.1 (15.71)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-11.1	16.7	0.0
	Q1, Q3	0.0, 0.0	-22.2, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-22, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	11.1 (0.00)	-16.7 (7.86)	16.7 (23.57)	0.0 (0.00)
	Median	11.1	-16.7	16.7	0.0
	Q1, Q3	11.1, 11.1	-22.2, -11.1	0.0, 33.3	0.0, 0.0
	Min, Max	11, 11	-22, -11	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	3.7 (6.42)	-14.8 (12.83)	0.0 (NE)	0.0 (NE)
	Median	0.0	-22.2	0.0	0.0
	Q1, Q3	0.0, 11.1	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 11	-22, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	7.4 (12.83)	-11.1 (11.11)	0.0 (NE)	0.0 (NE)
	Median	0.0	-11.1	0.0	0.0
	Q1, Q3	0.0, 22.2	-22.2, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 22	-22, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	11.1 (NE)	11.1 (NE)
	Median	0.0	0.0	11.1	11.1
	Q1, Q3	0.0, 0.0	0.0, 0.0	11.1, 11.1	11.1, 11.1
	Min, Max	0, 0	0, 0	11, 11	11, 11

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 40	n	0	0	1	1
	Mean (SD)			22.2 (NE)	22.2 (NE)
	Median			22.2	22.2
	Q1, Q3			22.2, 22.2	22.2, 22.2
	Min, Max			22, 22	22, 22
Cycle 42	n	1	1	1	1
	Mean (SD)	22.2 (NE)	-11.1 (NE)	0.0 (NE)	0.0 (NE)
	Median	22.2	-11.1	0.0	0.0
	Q1, Q3	22.2, 22.2	-11.1, -11.1	0.0, 0.0	0.0, 0.0
	Min, Max	22, 22	-11, -11	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			11.1 (NE)	11.1 (NE)
	Median			11.1	11.1
	Q1, Q3			11.1, 11.1	11.1, 11.1
	Min, Max			11, 11	11, 11
Cycle 46	n	1	1	1	1
	Mean (SD)	11.1 (NE)	-22.2 (NE)	22.2 (NE)	22.2 (NE)
	Median	11.1	-22.2	22.2	22.2
	Q1, Q3	11.1, 11.1	-22.2, -22.2	22.2, 22.2	22.2, 22.2
	Min, Max	11, 11	-22, -22	22, 22	22, 22
Cycle 48	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-22.2 (NE)		
	Median	11.1	-22.2		
	Q1, Q3	11.1, 11.1	-22.2, -22.2		
	Min, Max	11, 11	-22, -22		
Cycle 52	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		
Cycle 56	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	11.1 (NE)	-22.2 (NE)		
	Median	11.1	-22.2		
	Q1, Q3	11.1, 11.1	-22.2, -22.2		
	Min, Max	11, 11	-22, -22		
Cycle 66	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		
Cycle 70	n	1	1	0	0
	Mean (SD)	22.2 (NE)	-11.1 (NE)		
	Median	22.2	-11.1		
	Q1, Q3	22.2, 22.2	-11.1, -11.1		
	Min, Max	22, 22	-11, -11		
Cycle 72	n	1	1	0	0
	Mean (SD)	44.4 (NE)	11.1 (NE)		
	Median	44.4	11.1		
	Q1, Q3	44.4, 44.4	11.1, 11.1		
	Min, Max	44, 44	11, 11		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Pain

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	10.0 (16.10)	-2.2 (20.82)	23.6 (22.91)	1.4 (19.82)
	Median	0.0	0.0	11.1	0.0
	Q1, Q3	0.0, 11.1	-11.1, 11.1	5.6, 44.4	-11.1, 11.1
	Min, Max	0, 44	-44, 33	0, 67	-33, 44
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	20.4 (29.52)	8.3 (17.81)	35.9 (24.70)	13.1 (16.31)
	Median	5.6	0.0	33.3	11.1
	Q1, Q3	0.0, 27.8	0.0, 27.8	11.1, 44.4	0.0, 22.2
	Min, Max	0, 89	-22, 33	0, 89	0, 44

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	0.0 (0.00)		17.6 (33.58)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 0		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	17.8 (24.77)	0.0 (41.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	-100, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	21.2 (37.34)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	3.7 (11.11)	25.0 (40.51)	2.8 (43.71)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 50.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	12.1 (22.47)	-3.0 (34.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 67	-100, 33
Cycle 6	n	7	7	9	9
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (33.33)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 100	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	14.3 (37.80)	0.0 (57.74)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	-100, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	33.3 (57.74)	33.3 (57.74)	16.7 (23.57)	16.7 (23.57)
	Median	0.0	0.0	16.7	16.7
	Q1, Q3	0.0, 100.0	0.0, 100.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 33	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	44.4 (50.92)	44.4 (50.92)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 0	0, 0	0, 100	0, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	22.2 (19.25)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	16.7 (23.57)	0.0 (0.00)	0.0 (0.00)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	33.3 (57.74)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 100.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 100	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 66	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 70	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 72	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble swallowing saliva

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	13.3 (32.20)	13.3 (32.20)	41.7 (35.49)	25.0 (28.54)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	16.7, 66.7	0.0, 33.3
	Min, Max	0, 100	0, 100	0, 100	0, 100
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	41.7 (37.94)	41.7 (37.94)	56.9 (36.83)	39.2 (35.81)
	Median	33.3	33.3	66.7	33.3
	Q1, Q3	16.7, 66.7	16.7, 66.7	33.3, 100.0	0.0, 66.7
	Min, Max	0, 100	0, 100	0, 100	0, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	13.9 (22.29)		9.8 (15.66)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 67		0, 33	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	-6.7 (30.63)	17.8 (17.21)	6.7 (18.69)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 33	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	0.0 (0.00)	-13.3 (23.31)	24.2 (33.63)	18.2 (34.52)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	-67, 0	0, 100	0, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-11.1 (28.87)	19.4 (30.01)	13.9 (30.01)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	-67, 33	0, 100	0, 100
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (17.25)	-4.2 (27.82)	15.2 (22.92)	9.1 (21.56)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	9.5 (16.27)	0.0 (0.00)	11.1 (16.67)	7.4 (14.70)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 0	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-14.3 (32.53)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-67, 33	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (27.22)	11.1 (17.21)	5.6 (13.61)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-16.7, 16.7	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	6.7 (14.91)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (0.00)	-11.1 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 0	-67, 0	0, 0	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (47.14)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-33.3	16.7	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	0.0 (0.00)	-22.2 (38.49)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
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For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 42	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-66.7 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, -66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, -67	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-66.7 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	-66.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, -66.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	-67, -67	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 52	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 66	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 70	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 72	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Choked when swallowing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	6.7 (14.05)	-6.7 (30.63)	27.1 (27.81)	16.7 (29.81)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 100	0, 100
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	19.4 (17.16)	5.6 (23.92)	35.3 (24.92)	25.5 (30.11)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	22.2 (32.82)		15.7 (29.15)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 33.3		0.0, 33.3	
	Min, Max	0, 100		0, 100	
Cycle 2	n	10	10	15	15
	Mean (SD)	23.3 (31.62)	6.7 (21.08)	31.1 (29.46)	13.3 (24.56)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	-33, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	20.0 (17.21)	3.3 (24.60)	27.3 (29.13)	12.1 (16.82)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	25.9 (22.22)	7.4 (14.70)	30.6 (30.01)	16.7 (22.47)
	Median	33.3	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	0, 33	0, 100	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	16.7 (25.20)	0.0 (17.82)	24.2 (26.21)	18.2 (22.92)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	19.0 (26.23)	9.5 (25.20)	25.9 (22.22)	18.5 (17.57)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	14.3 (17.82)	0.0 (19.25)	9.5 (16.27)	4.8 (12.60)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 33	0, 33	0, 33
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (47.14)	16.7 (27.89)	11.1 (17.21)
	Median	16.7	16.7	0.0	0.0
	Q1, Q3	0.0, 50.0	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-67, 33	0, 67	0, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	33.3 (33.33)	0.0 (33.33)	20.0 (18.26)	13.3 (18.26)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-67, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	50.0 (23.57)	33.3 (0.00)
	Median	0.0	0.0	50.0	33.3
	Q1, Q3	0.0, 33.3	-66.7, 0.0	33.3, 66.7	33.3, 33.3
	Min, Max	0, 33	-67, 0	33, 67	33, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (33.33)	33.3 (33.33)	22.2 (38.49)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 0.0	-66.7, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-67, 0	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	-22.2 (38.49)	44.4 (50.92)	33.3 (57.74)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-66.7, 0.0	0.0, 100.0	0.0, 100.0
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (33.33)	0.0 (0.00)	33.3 (33.33)	22.2 (38.49)
	Median	33.3	0.0	33.3	0.0
	Q1, Q3	0.0, 66.7	0.0, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 67	0, 0	0, 67	0, 67
Cycle 24	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (47.14)	22.2 (19.25)	11.1 (19.25)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	33.3 (33.33)	22.2 (38.49)
	Median	0.0	-16.7	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 66.7	0.0, 66.7
	Min, Max	0, 0	-33, 0	0, 67	0, 67
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	50.0 (23.57)	33.3 (47.14)
	Median	0.0	-16.7	50.0	33.3
	Q1, Q3	0.0, 0.0	-33.3, 0.0	33.3, 66.7	0.0, 66.7
	Min, Max	0, 0	-33, 0	33, 67	0, 67
Cycle 30	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	-33.3 (0.00)	33.3 (0.00)	16.7 (23.57)
	Median	16.7	-33.3	33.3	16.7
	Q1, Q3	0.0, 33.3	-33.3, -33.3	33.3, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, -33	33, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 66.7	-33.3, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 67	-33, 0	33, 33	33, 33
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-22.2 (19.25)	66.7 (NE)	66.7 (NE)
	Median	0.0	-33.3	66.7	66.7
	Q1, Q3	0.0, 33.3	-33.3, 0.0	66.7, 66.7	66.7, 66.7
	Min, Max	0, 33	-33, 0	67, 67	67, 67
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	0.0	33.3	33.3
	Q1, Q3	66.7, 66.7	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	0, 0	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	66.7 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	0.0	33.3	33.3
	Q1, Q3	66.7, 66.7	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	66.7 (NE)	0.0 (NE)		
	Median	66.7	0.0		
	Q1, Q3	66.7, 66.7	0.0, 0.0		
	Min, Max	67, 67	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	100.0 (NE)	33.3 (NE)		
	Median	100.0	33.3		
	Q1, Q3	100.0, 100.0	33.3, 33.3		
	Min, Max	100, 100	33, 33		
Cycle 56	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-66.7 (NE)		
	Median	0.0	-66.7		
	Q1, Q3	0.0, 0.0	-66.7, -66.7		
	Min, Max	0, 0	-67, -67		
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 70	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-33.3 (NE)		
	Median	33.3	-33.3		
	Q1, Q3	33.3, 33.3	-33.3, -33.3		
	Min, Max	33, 33	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Dry mouth

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	20.0 (23.31)	3.3 (29.19)	35.4 (35.42)	18.8 (32.13)
	Median	16.7	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 50.0
	Min, Max	0, 67	-33, 33	0, 100	-33, 67
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	47.2 (22.29)	25.0 (20.72)	49.0 (33.58)	33.3 (31.18)
	Median	33.3	33.3	33.3	33.3
	Q1, Q3	33.3, 66.7	33.3, 33.3	33.3, 66.7	0.0, 66.7
	Min, Max	33, 100	-33, 33	0, 100	0, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable.

Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.

For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	11.1 (29.59)		9.8 (19.60)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 0.0	
	Min, Max	0, 100		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	24.4 (29.46)	13.3 (24.56)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	3.3 (10.54)	-6.7 (34.43)	27.3 (35.96)	15.2 (37.61)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-100, 33	0, 100	-33, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	-3.7 (26.06)	30.6 (36.12)	19.4 (26.43)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 100	0, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	12.5 (24.80)	0.0 (17.82)	27.3 (29.13)	21.2 (30.81)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	37.0 (35.14)	33.3 (33.33)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 100	0, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (25.20)	23.8 (37.09)	19.0 (37.80)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 0	0, 100	0, 100
Cycle 10	n	4	4	6	6
	Mean (SD)	25.0 (31.91)	0.0 (27.22)	16.7 (40.82)	11.1 (27.22)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 50.0	-16.7, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 67	-33, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	22.2 (19.25)	-11.1 (50.92)	20.0 (29.81)	13.3 (18.26)
	Median	33.3	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-66.7, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-67, 33	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-33.3 (57.74)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 67	-33, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	22.2 (38.49)	-11.1 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 66.7	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 67	-33, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 0	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 33	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-50.0 (70.71)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	-50.0	16.7	0.0
	Q1, Q3	0.0, 0.0	-100.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-100, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	33.3 (57.74)	0.0 (0.00)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 100	0, 0	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 0	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			0.0 (NE)	0.0 (NE)
	Median			0.0	0.0
	Q1, Q3			0.0, 0.0	0.0, 0.0
	Min, Max			0, 0	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	66.7 (NE)	-33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	66.7	-33.3	33.3	33.3
	Q1, Q3	66.7, 66.7	-33.3, -33.3	33.3, 33.3	33.3, 33.3
	Min, Max	67, 67	-33, -33	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	100.0 (NE)	0.0 (NE)	0.0 (NE)	0.0 (NE)
	Median	100.0	0.0	0.0	0.0
	Q1, Q3	100.0, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	100, 100	0, 0	0, 0	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	33.3 (NE)	-66.7 (NE)		
	Median	33.3	-66.7		
	Q1, Q3	33.3, 33.3	-66.7, -66.7		
	Min, Max	33, 33	-67, -67		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 66	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		
Cycle 70	n	1	1	0	0
	Mean (SD)	66.7 (NE)	-33.3 (NE)		
	Median	66.7	-33.3		
	Q1, Q3	66.7, 66.7	-33.3, -33.3		
	Min, Max	67, 67	-33, -33		
Cycle 72	n	1	1	0	0
	Mean (SD)	100.0 (NE)	0.0 (NE)		
	Median	100.0	0.0		
	Q1, Q3	100.0, 100.0	0.0, 0.0		
	Min, Max	100, 100	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with taste

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	13.3 (32.20)	3.3 (10.54)	27.1 (34.89)	18.8 (29.74)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 100	0, 33	0, 100	0, 100
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	16.7 (30.15)	5.6 (19.25)	51.0 (37.49)	41.2 (32.34)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 16.7	33.3, 100.0	33.3, 66.7
	Min, Max	0, 100	-33, 33	0, 100	0, 100

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	2.8 (9.62)		13.7 (23.74)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 0.0		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	13.3 (21.08)	0.0 (17.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	6.7 (14.05)	15.2 (22.92)	0.0 (25.82)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	7.4 (14.70)	7.4 (14.70)	19.4 (26.43)	5.6 (19.25)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 33	0, 33	0, 67	-33, 33
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	4.2 (11.79)	15.2 (22.92)	6.1 (25.03)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	4.8 (12.60)	11.1 (23.57)	0.0 (16.67)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 67	-33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	4.8 (12.60)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	8.3 (16.67)	8.3 (16.67)	16.7 (40.82)	11.1 (27.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 100	0, 67
Cycle 12	n	3	3	5	5
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	20.0 (29.81)	13.3 (18.26)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	33.3 (47.14)	16.7 (23.57)
	Median	0.0	0.0	33.3	16.7
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 0	0, 0	0, 67	0, 33
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	22.2 (19.25)	11.1 (19.25)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 33	0, 33
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	0.0 (0.00)	16.7 (23.57)	0.0 (0.00)
	Median	0.0	0.0	16.7	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	0, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	11.1 (19.25)	0.0 (NE)	0.0 (NE)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	0, 33	0, 0	0, 0
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 40	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	33.3 (NE)	33.3 (NE)	33.3 (NE)
	Median	33.3	33.3	33.3	33.3
	Q1, Q3	33.3, 33.3	33.3, 33.3	33.3, 33.3	33.3, 33.3
	Min, Max	33, 33	33, 33	33, 33	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	33.3 (NE)
	Median			33.3	33.3
	Q1, Q3			33.3, 33.3	33.3, 33.3
	Min, Max			33, 33	33, 33
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	33.3 (NE)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
	Min, Max	0, 0	0, 0	33, 33	33, 33
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 66	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 70	n	1	1	0	0
	Mean (SD)	0.0 (NE)	0.0 (NE)		
	Median	0.0	0.0		
	Q1, Q3	0.0, 0.0	0.0, 0.0		
	Min, Max	0, 0	0, 0		
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	33.3 (NE)		
	Median	33.3	33.3		
	Q1, Q3	33.3, 33.3	33.3, 33.3		
	Min, Max	33, 33	33, 33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: Trouble with coughing

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	3.3 (10.54)	3.3 (10.54)	27.1 (27.81)	12.5 (26.87)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 50.0	0.0, 33.3
	Min, Max	0, 33	0, 33	0, 67	-33, 67
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	13.9 (17.16)	11.1 (21.71)	39.2 (33.82)	25.5 (27.71)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 33	0, 100	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	8.3 (15.08)		15.7 (23.91)	
	Median	0.0		0.0	
	Q1, Q3	0.0, 16.7		0.0, 33.3	
	Min, Max	0, 33		0, 67	
Cycle 2	n	10	10	15	15
	Mean (SD)	3.3 (10.54)	-6.7 (14.05)	20.0 (27.60)	4.4 (27.79)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 3	n	10	10	11	11
	Mean (SD)	6.7 (14.05)	-3.3 (10.54)	18.2 (22.92)	6.1 (20.10)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 67	0, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	3.7 (11.11)	-7.4 (14.70)	19.4 (30.01)	2.8 (22.29)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 100	-33, 67
Cycle 5	n	8	8	11	11
	Mean (SD)	4.2 (11.79)	-8.3 (15.43)	21.2 (26.97)	6.1 (32.72)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 67	-67, 67
Cycle 6	n	7	7	9	9
	Mean (SD)	4.8 (12.60)	-4.8 (12.60)	11.1 (16.67)	-7.4 (22.22)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	4.8 (12.60)	-9.5 (16.27)	9.5 (16.27)	-9.5 (25.20)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-67, 0
Cycle 10	n	4	4	6	6
	Mean (SD)	16.7 (19.25)	0.0 (0.00)	11.1 (27.22)	-11.1 (34.43)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 67	-67, 33
Cycle 12	n	3	3	5	5
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	6.7 (14.91)	-6.7 (14.91)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0
	Min, Max	0, 33	-33, 0	0, 33	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	0.0 (0.00)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, 0	0, 33	0, 0
Cycle 16	n	3	3	2	2
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	16.7 (23.57)	-16.7 (23.57)
	Median	0.0	-33.3	16.7	-16.7
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 18	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
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unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 22	n	3	3	3	3
	Mean (SD)	0.0 (0.00)	-22.2 (19.25)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-33.3	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0
Cycle 24	n	2	2	3	3
	Mean (SD)	0.0 (0.00)	-16.7 (23.57)	11.1 (19.25)	-11.1 (19.25)
	Median	0.0	-16.7	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, 0	0, 33	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	2	2	3	3
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	11.1 (19.25)	-11.1 (19.25)
	Median	16.7	0.0	0.0	0.0
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 33	-33, 0
Cycle 28	n	2	2	2	2
	Mean (SD)	16.7 (23.57)	0.0 (0.00)	16.7 (23.57)	-16.7 (23.57)
	Median	16.7	0.0	16.7	-16.7
	Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 33	0, 0	0, 33	-33, 0
Cycle 30	n	2	2	2	2
	Mean (SD)	0.0 (0.00)	-33.3 (0.00)	16.7 (23.57)	-16.7 (23.57)
	Median	0.0	-33.3	16.7	-16.7
	Q1, Q3	0.0, 0.0	-33.3, -33.3	0.0, 33.3	-33.3, 0.0
	Min, Max	0, 0	-33, -33	0, 33	-33, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (NE)	-33.3 (NE)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 34	n	3	3	1	1
	Mean (SD)	11.1 (19.25)	-11.1 (19.25)	0.0 (NE)	-33.3 (NE)
	Median	0.0	0.0	0.0	-33.3
	Q1, Q3	0.0, 33.3	-33.3, 0.0	0.0, 0.0	-33.3, -33.3
	Min, Max	0, 33	-33, 0	0, 0	-33, -33
Cycle 36	n	1	1	1	1
	Mean (SD)	0.0 (NE)	0.0 (NE)	33.3 (NE)	0.0 (NE)
	Median	0.0	0.0	33.3	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0
	Min, Max	0, 0	0, 0	33, 33	0, 0

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
Cycle 40	n	0	0	1	1
	Mean (SD)			0.0 (NE)	-33.3 (NE)
	Median			0.0	-33.3
	Q1, Q3			0.0, 0.0	-33.3, -33.3
	Min, Max			0, 0	-33, -33
Cycle 42	n	1	1	1	1
	Mean (SD)	33.3 (NE)	0.0 (NE)	66.7 (NE)	33.3 (NE)
	Median	33.3	0.0	66.7	33.3
	Q1, Q3	33.3, 33.3	0.0, 0.0	66.7, 66.7	33.3, 33.3
	Min, Max	33, 33	0, 0	67, 67	33, 33

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	0	0	1	1
	Mean (SD)			33.3 (NE)	0.0 (NE)
	Median			33.3	0.0
	Q1, Q3			33.3, 33.3	0.0, 0.0
	Min, Max			33, 33	0, 0
Cycle 46	n	1	1	1	1
	Mean (SD)	0.0 (NE)	-33.3 (NE)	33.3 (NE)	0.0 (NE)
	Median	0.0	-33.3	33.3	0.0
	Q1, Q3	0.0, 0.0	-33.3, -33.3	33.3, 33.3	0.0, 0.0
	Min, Max	0, 0	-33, -33	33, 33	0, 0
Cycle 48	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 52	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		
Cycle 56	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 58	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		
Cycle 64	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 66	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 70	n	1	1	0	0
	Mean (SD)	0.0 (NE)	-33.3 (NE)		
	Median	0.0	-33.3		
	Q1, Q3	0.0, 0.0	-33.3, -33.3		
	Min, Max	0, 0	-33, -33		
Cycle 72	n	1	1	0	0
	Mean (SD)	33.3 (NE)	0.0 (NE)		
	Median	33.3	0.0		
	Q1, Q3	33.3, 33.3	0.0, 0.0		
	Min, Max	33, 33	0, 0		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: Trouble talking

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	0.0 (0.00)	-10.0 (16.10)	18.8 (24.25)	2.1 (25.73)
	Median	0.0	0.0	0.0	0.0
	Q1, Q3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 16.7
	Min, Max	0, 0	-33, 0	0, 67	-67, 33
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	5.6 (12.97)	-2.8 (9.62)	39.2 (35.81)	23.5 (28.30)
	Median	0.0	0.0	33.3	33.3
	Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 33.3
	Min, Max	0, 33	-33, 0	0, 100	-33, 67

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-3-1-qs-chg-oes-pop1-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	53.70 (36.03)	-8.93 (6.75)	17	58.17 (33.22)	-12.75 (5.13)	3.82 (-11.92, 19.56)	0.21 (-0.64, 1.06)	0.6191

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Eating									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	27.08 (30.18)	-11.10 (6.84)	17	29.41 (24.32)	3.42 (5.04)	-14.52 (-30.47, 1.44)	-0.75 (-1.59, 0.09)	0.0723

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Reflux									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	4.17 (10.36)	-3.87 (2.35)	17	12.75 (20.01)	4.72 (1.91)	-8.58 (-14.10, -3.06)	-1.52 (-2.56, -0.48)	0.0036

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Pain (OES18)									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	12.04 (18.02)	-8.04 (3.89)	17	22.88 (20.21)	-0.52 (3.02)	-7.52 (-16.84, 1.80)	-0.73 (-1.63, 0.18)	0.1083

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-3-1-1-eff-mmrmqs-oes-pop1-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble swallowing saliva									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	0.00 (0.00)	-1.67 (6.34)	17	17.65 (33.58)	5.04 (5.07)	-6.71 (-21.97, 8.55)	-0.39 (-1.27, 0.49)	0.3700

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Choked when swallowing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	13.89 (22.29)	-8.65 (5.46)	17	9.80 (15.66)	9.96 (4.07)	-18.61 (-31.24, -5.97)	-1.30 (-2.25, -0.35)	0.0060

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dry mouth									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	22.22 (32.82)	7.19 (5.42)	17	15.69 (29.15)	13.10 (4.12)	-5.91 (-18.43, 6.62)	-0.42 (-1.31, 0.46)	0.3397

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with taste									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	11.11 (29.59)	-12.08 (7.60)	17	9.80 (19.60)	9.77 (5.46)	-21.84 (-38.98, -4.70)	-1.08 (-1.97, -0.19)	0.0149

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with coughing									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	2.78 (9.62)	-0.18 (5.25)	17	13.73 (23.74)	4.28 (3.89)	-4.46 (-17.06, 8.14)	-0.32 (-1.20, 0.57)	0.4723

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble talking									
Cycle 6	7		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	8.33 (15.08)	-3.39 (5.29)	17	15.69 (23.91)	7.76 (3.93)	-11.15 (-23.89, 1.59)	-0.76 (-1.64, 0.12)	0.0818

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab+chemotherapy.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+chemotherapy arm. Negative differences favor tislelizumab+chemotherapy.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	13	7 (53.8)	2.9 (0.1, NE)	17	5 (29.4)	NR (6.4, NE)	3.765 (0.748, 18.944)	0.0754
Eating	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	NR (0.8, NE)	0.269 (0.030, 2.390)	0.2122
Reflux	13	3 (23.1)	56.5 (1.9, NE)	17	6 (35.3)	NR (1.4, NE)	0.499 (0.090, 2.772)	0.4197
Pain	13	2 (15.4)	56.5 (NE, NE)	17	5 (29.4)	24.4 (0.8, NE)	0.648 (0.055, 7.567)	0.7273
Trouble Swallowing Saliva	13	1 (7.7)	NR (NE, NE)	17	7 (41.2)	29.9 (1.0, NE)	0.242 (0.026, 2.297)	0.1857
Choked When Swallowing	13	1 (7.7)	NR (2.3, NE)	17	5 (29.4)	NR (1.5, NE)	0.324 (0.035, 3.050)	0.3032

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dry Mouth	13	3 (23.1)	NR (2.3, NE)	17	9 (52.9)	2.2 (0.7, NE)	0.393 (0.095, 1.630)	0.1859
Trouble With Taste	13	2 (15.4)	NR (2.8, NE)	17	8 (47.1)	3.3 (0.8, NE)	0.279 (0.056, 1.384)	0.0975
Trouble With Coughing	13	3 (23.1)	26.0 (0.7, NE)	17	4 (23.5)	NR (2.2, NE)	0.648 (0.103, 4.061)	0.6402
Trouble Talking	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (3.2, NE)	0.000 (0.000, NE)	0.2489

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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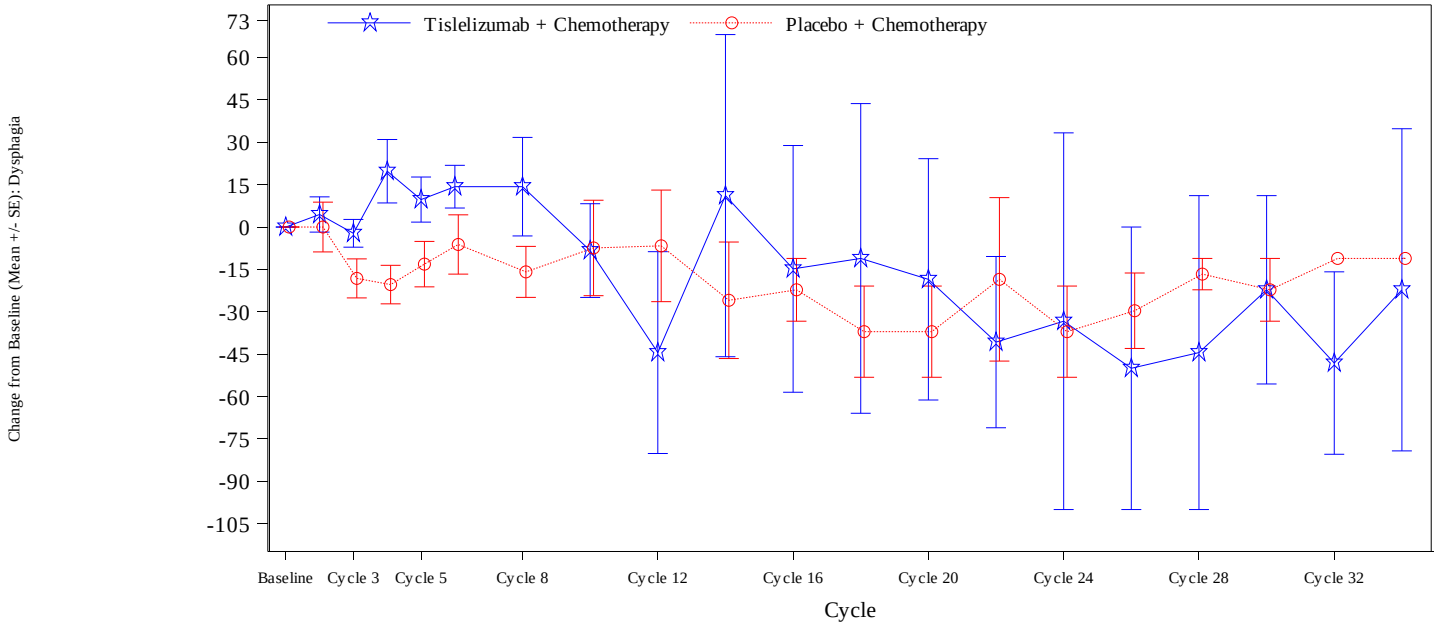
Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

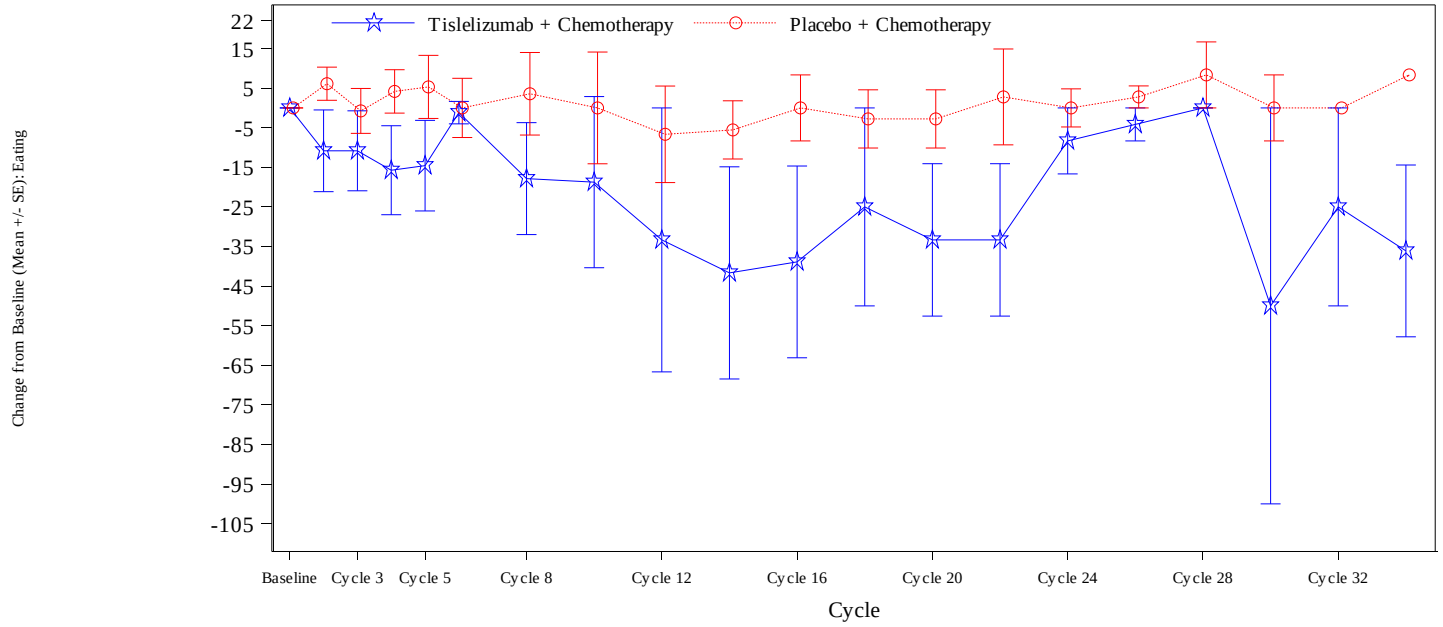


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-series.sas 26NOV2024 21:27 f-14-2-7-2-series-o18-pop1-cl.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

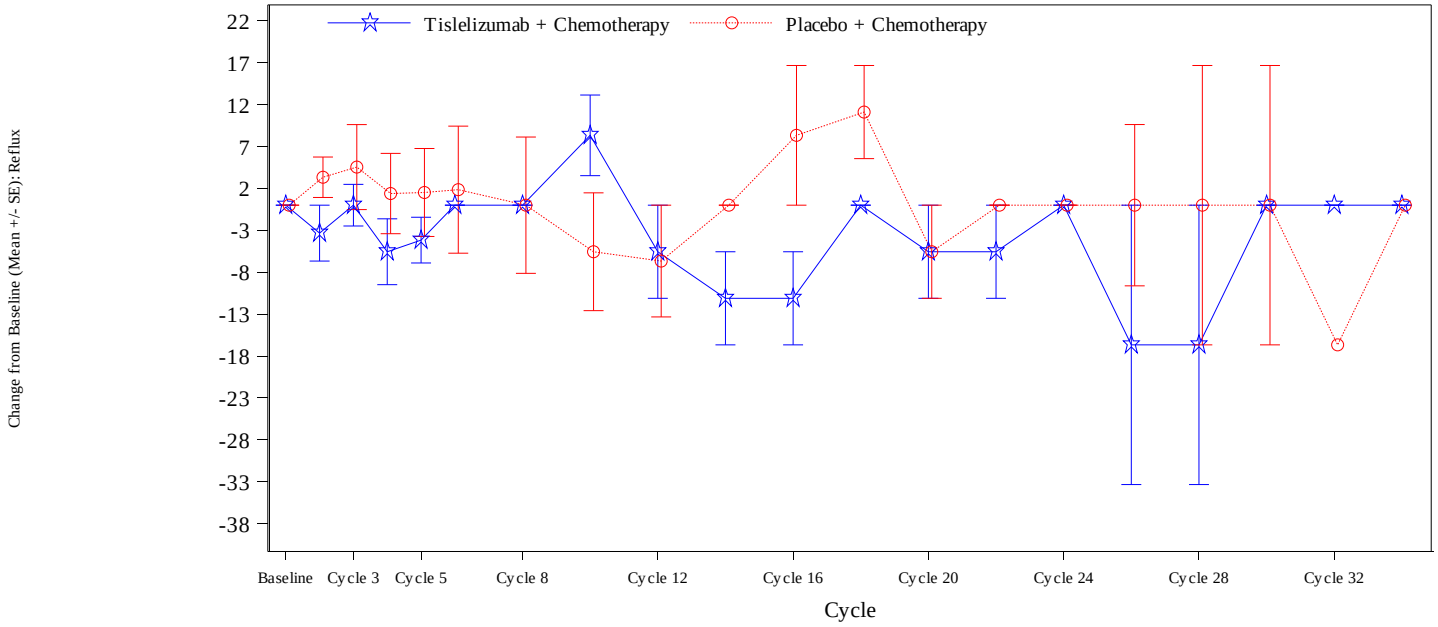


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-series.sas 26NOV2024 21:27 f-14-2-7-2-series-o18-pop1-cl.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

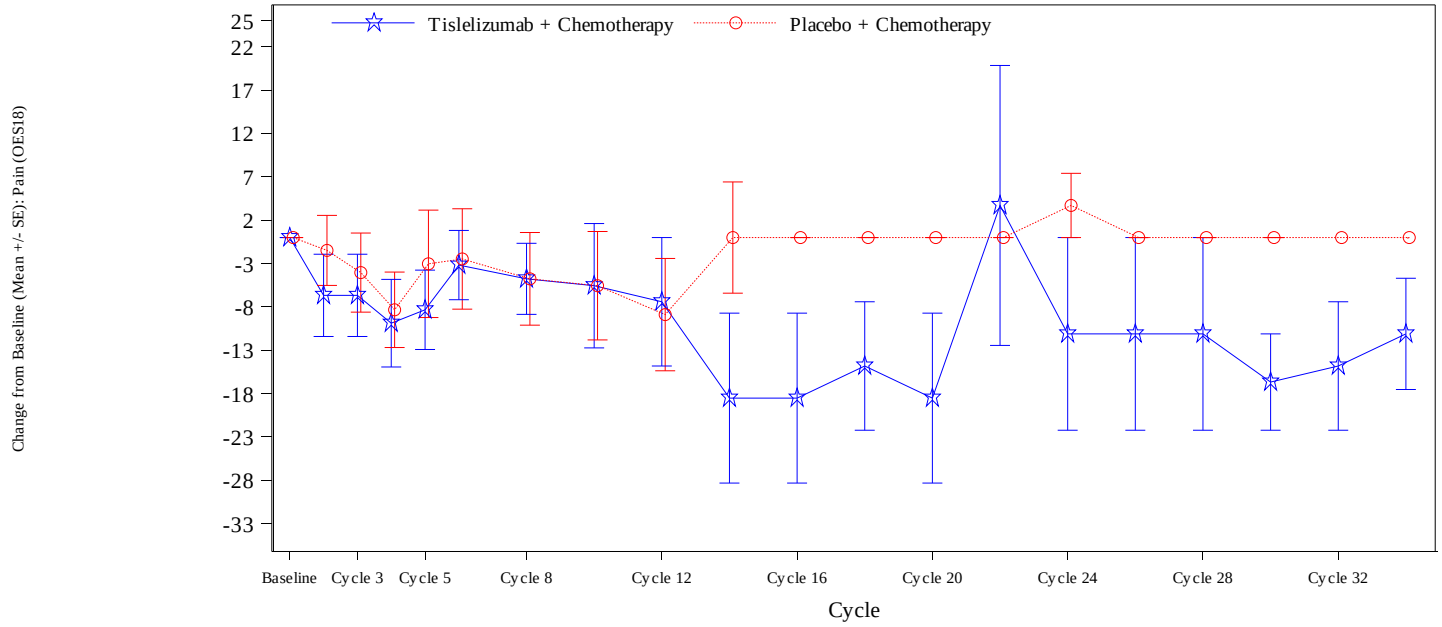


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-series.sas 26NOV2024 21:27 f-14-2-7-2-series-o18-pop1-cl.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

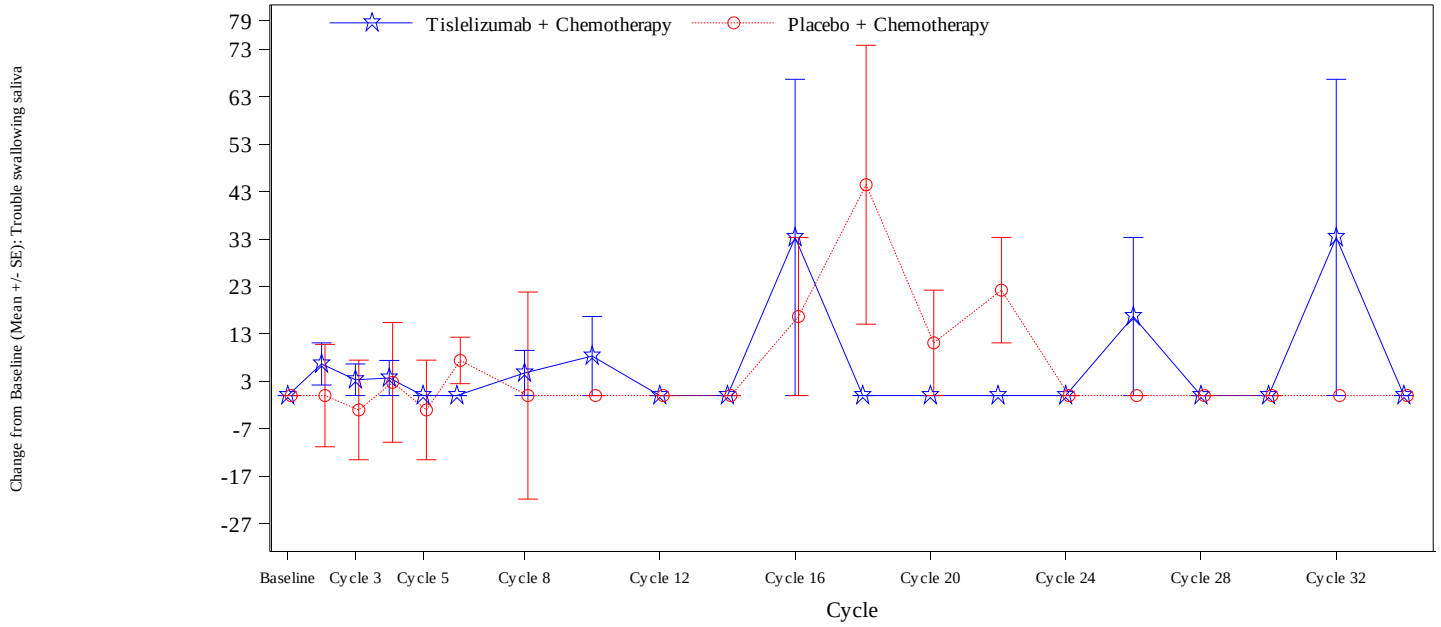


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-series.sas 26NOV2024 21:27 f-14-2-7-2-series-o18-pop1-cl.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

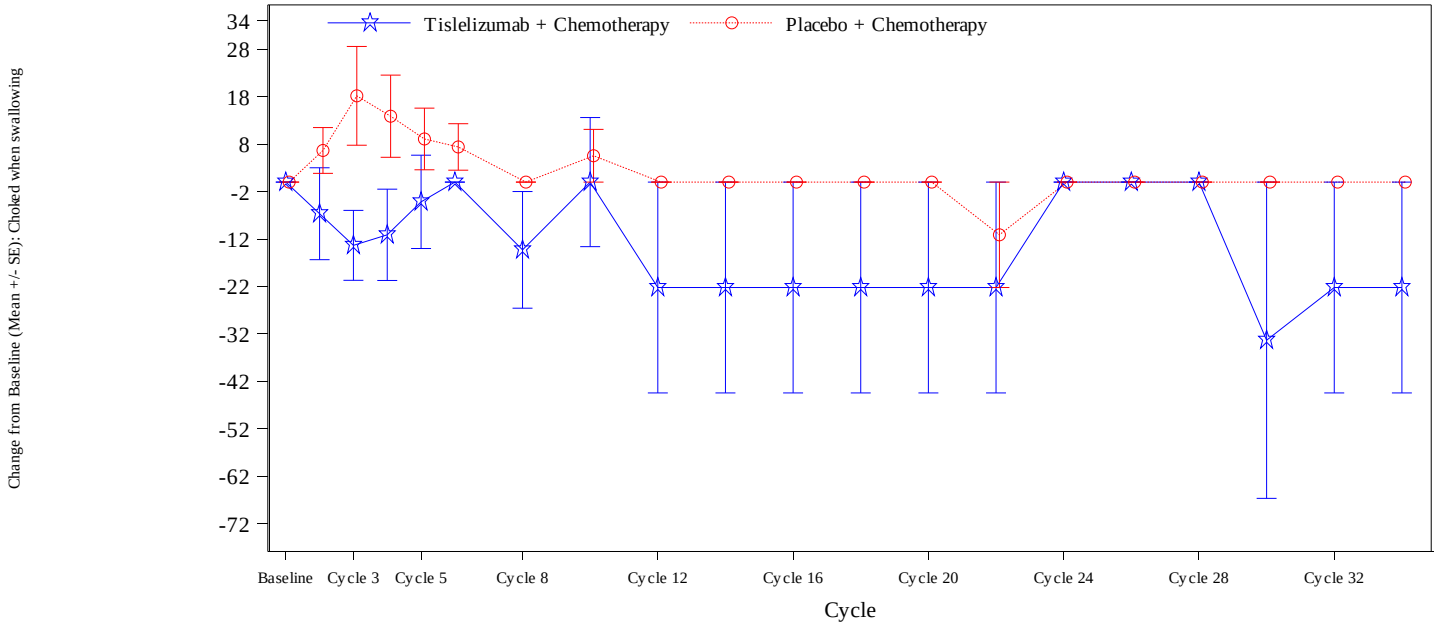


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores for dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-series.sas 26NOV2024 21:27 f-14-2-7-2-series-o18-pop1-cl.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
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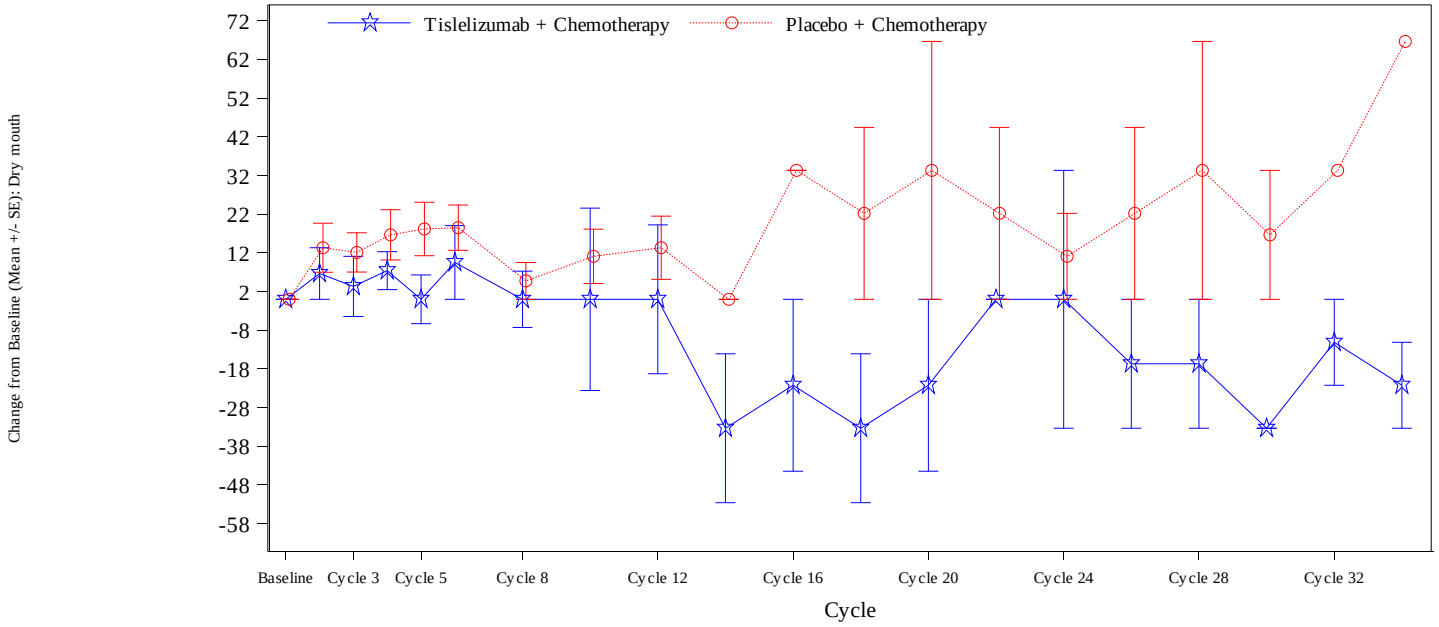

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Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
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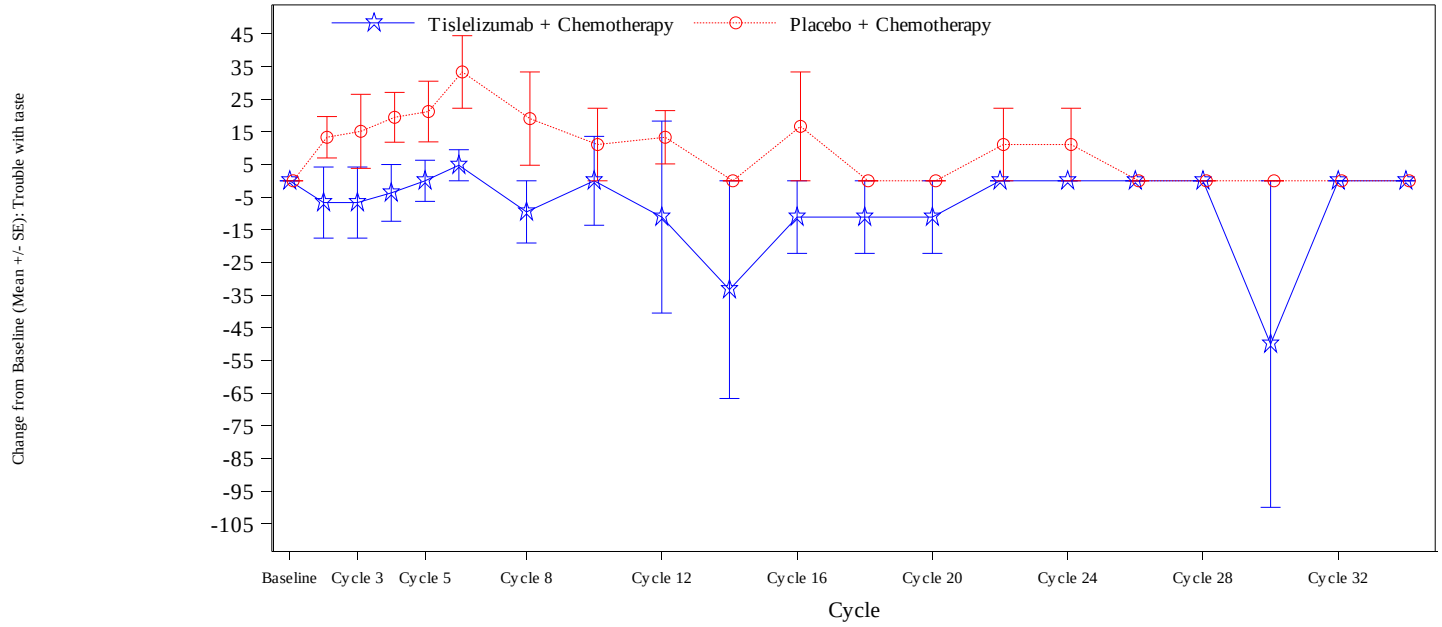

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Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

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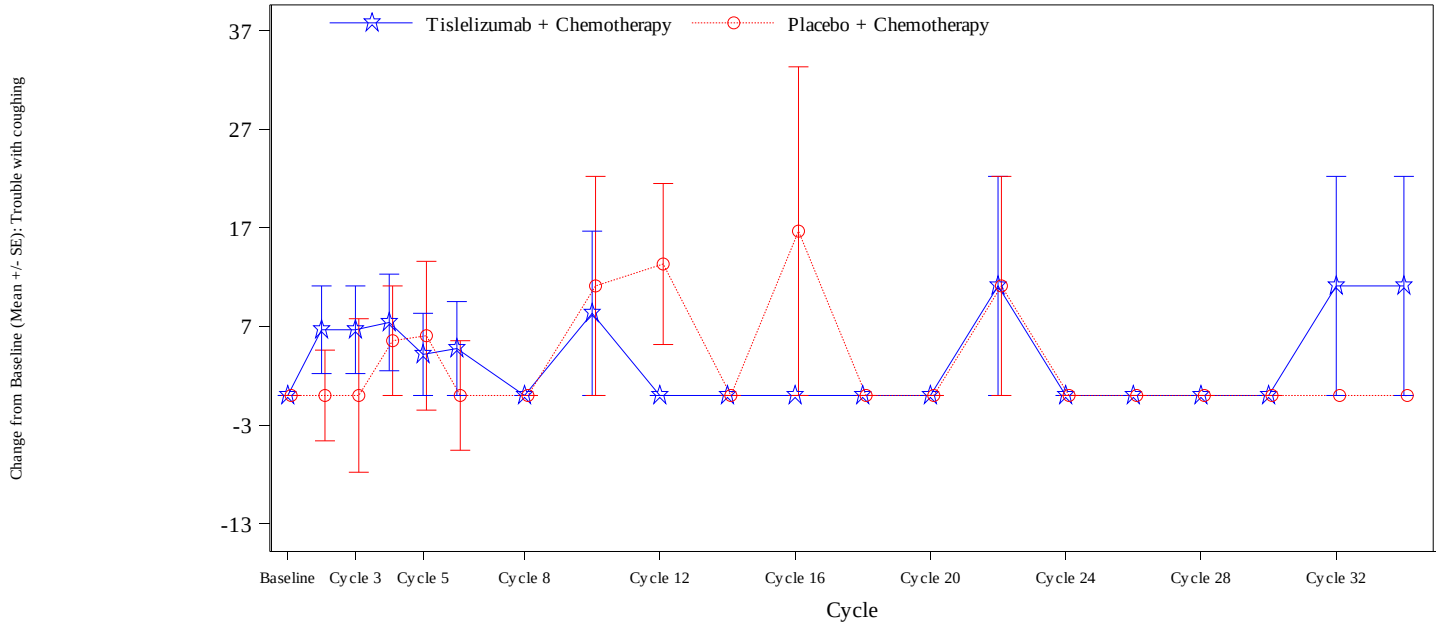

No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
Placebo + Chemotherapy	17	15	11	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

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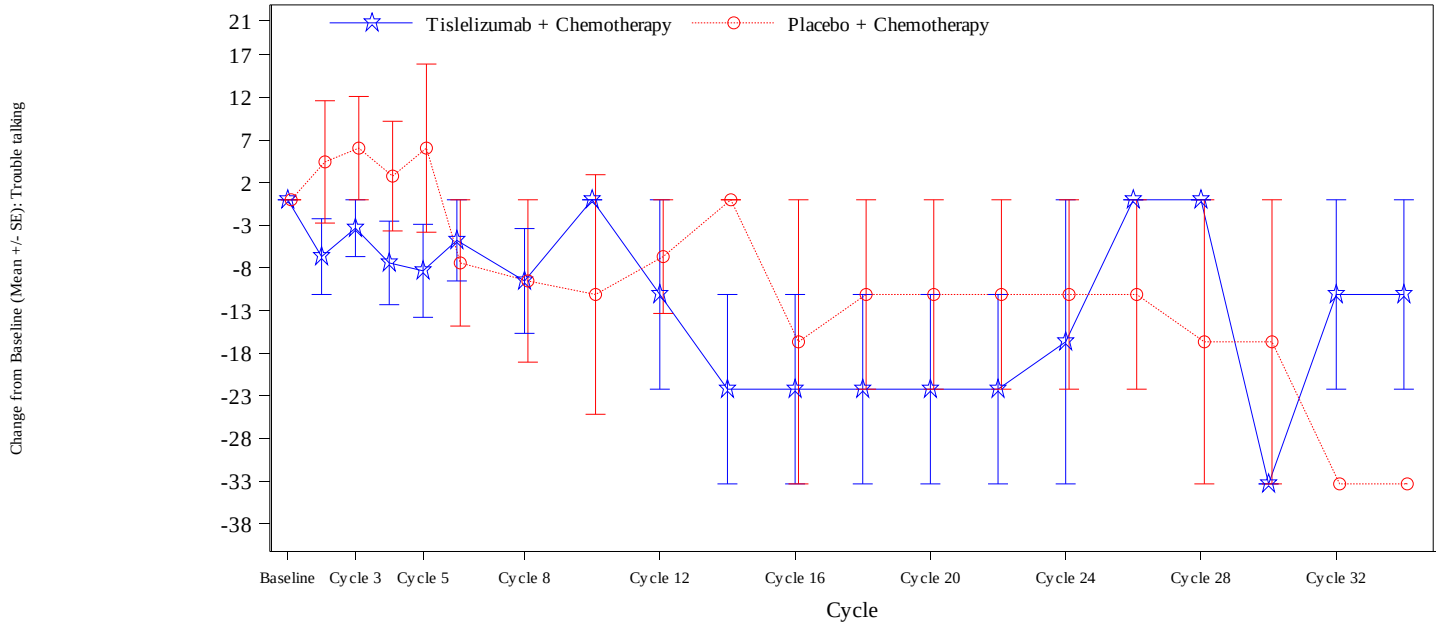

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Tislelizumab + Chemotherapy	12	10	10	9	8	7	7	4	3	3	3	3	3	3	2	2	2	2	3	3
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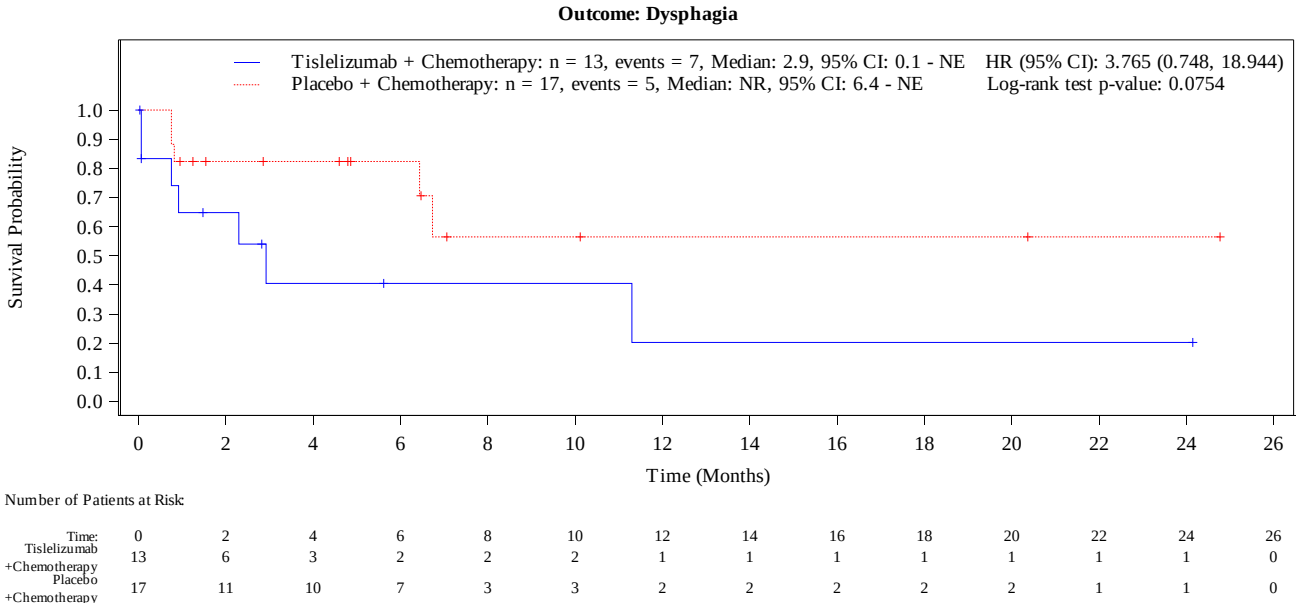
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
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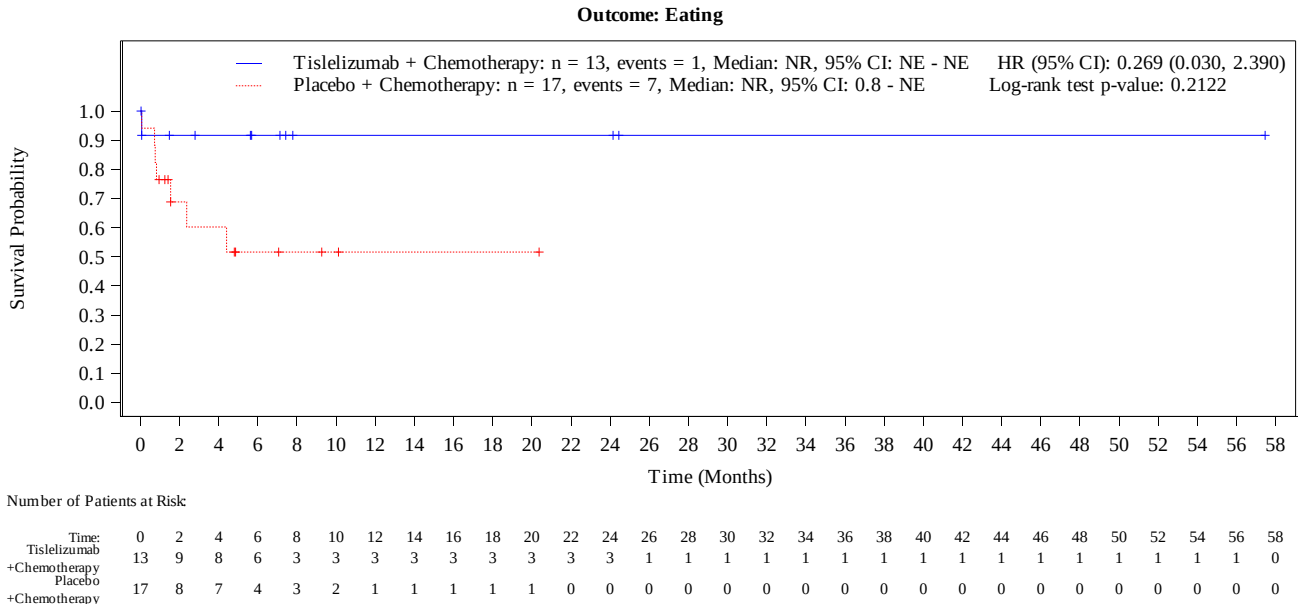
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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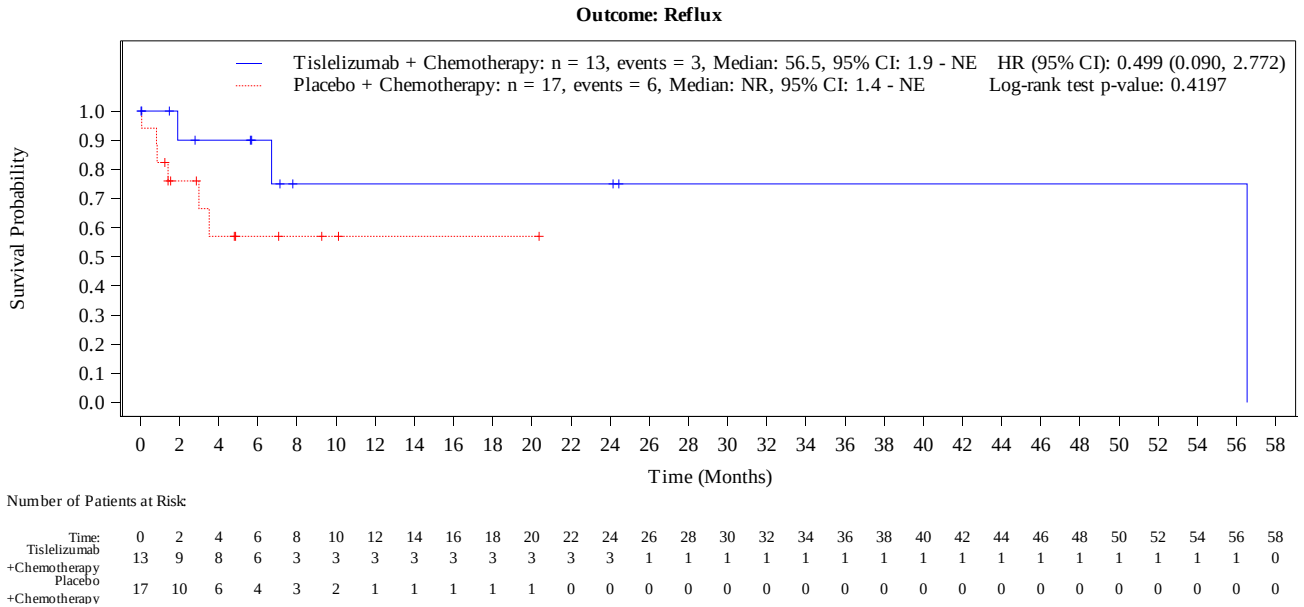

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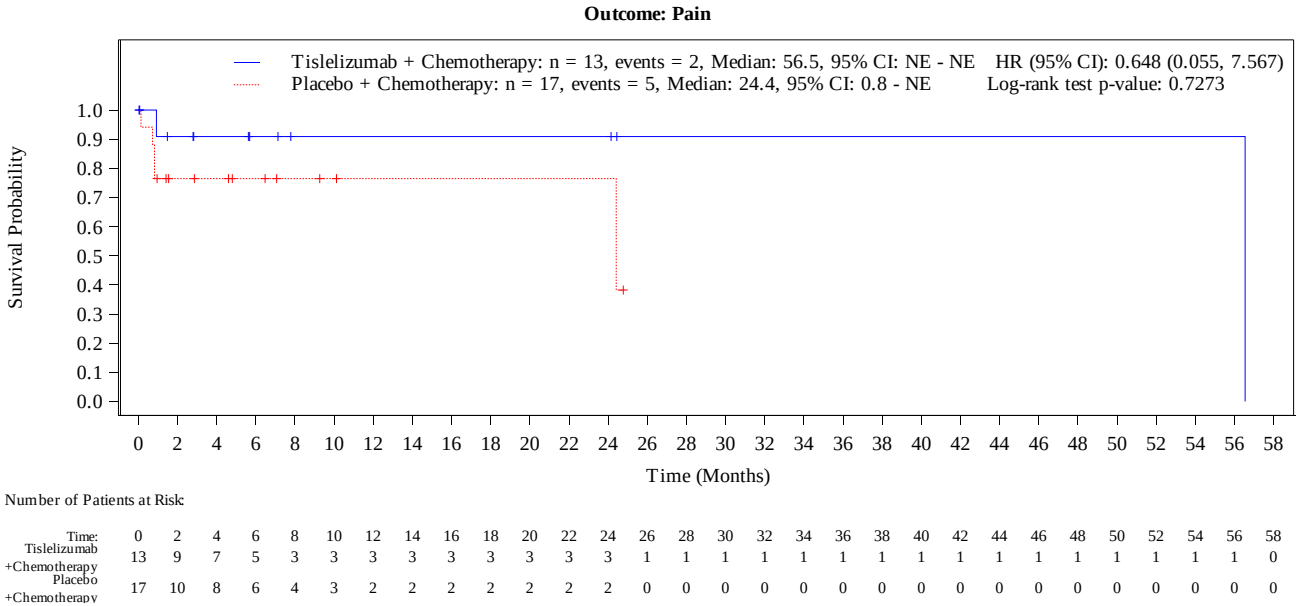

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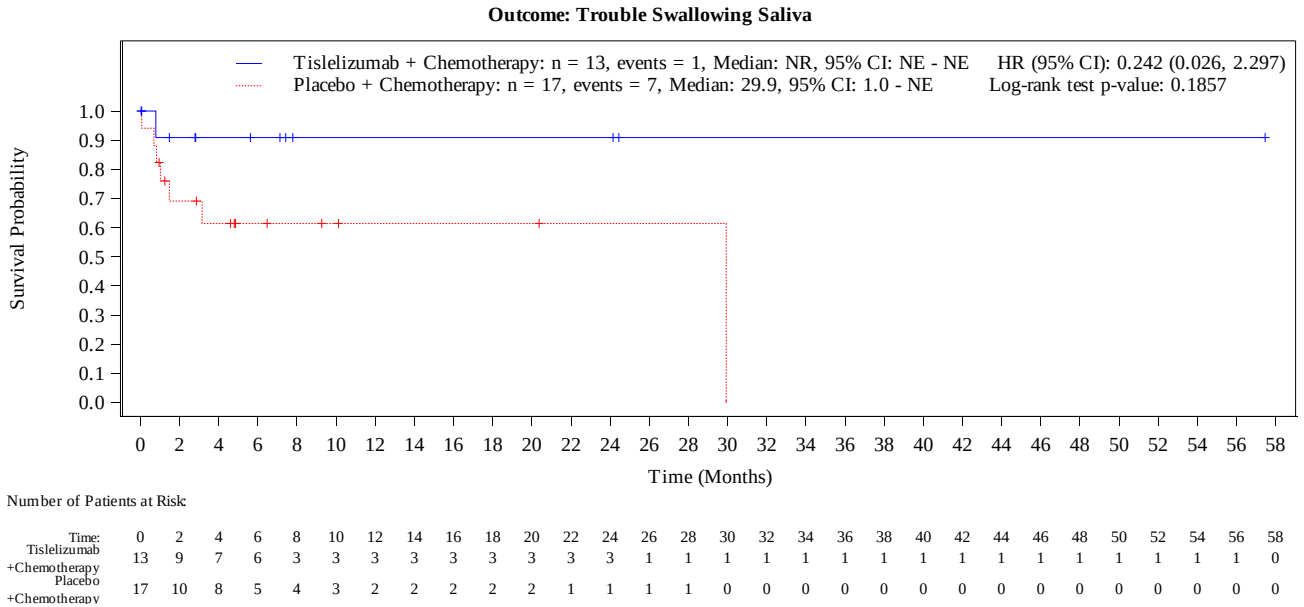
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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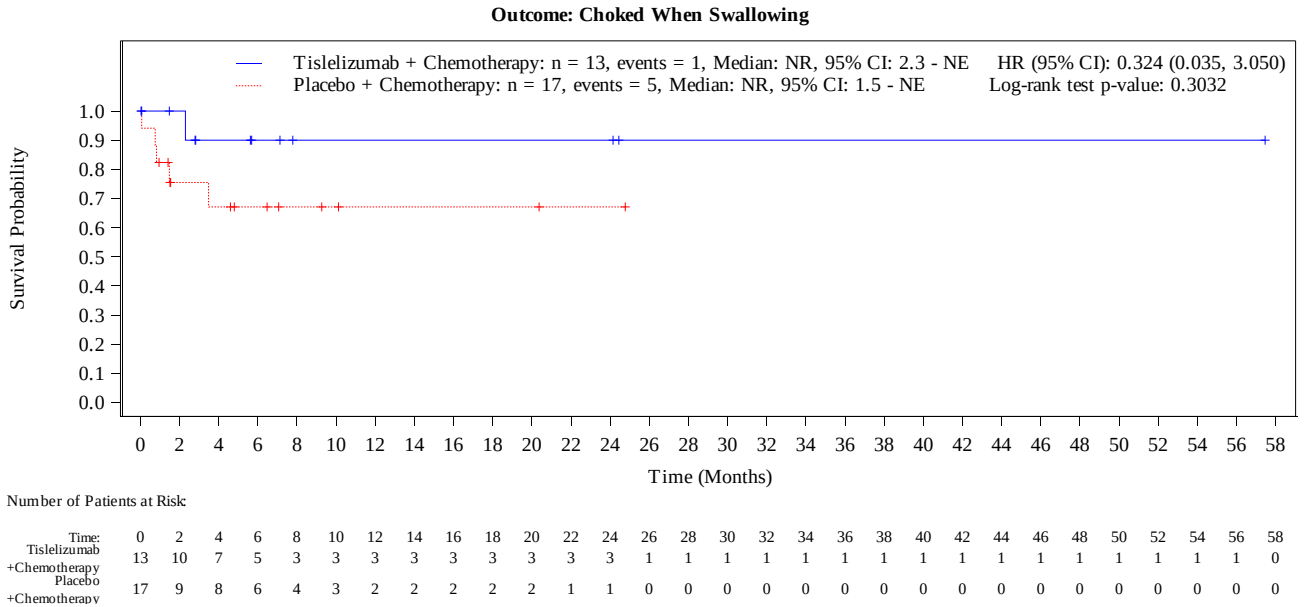

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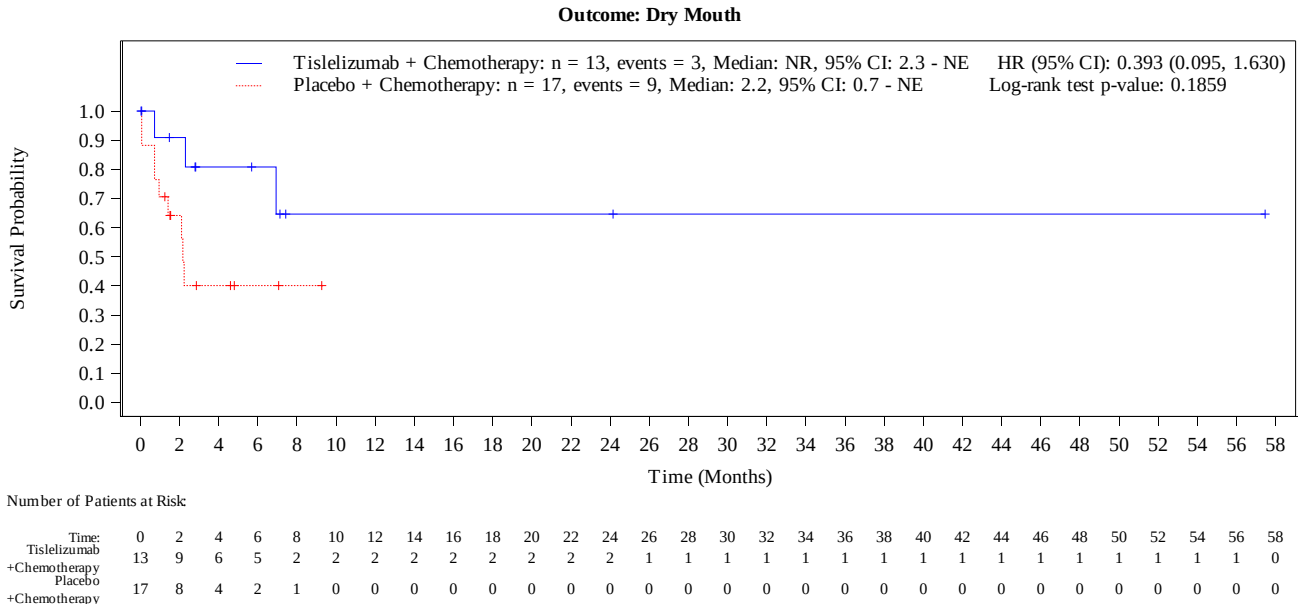

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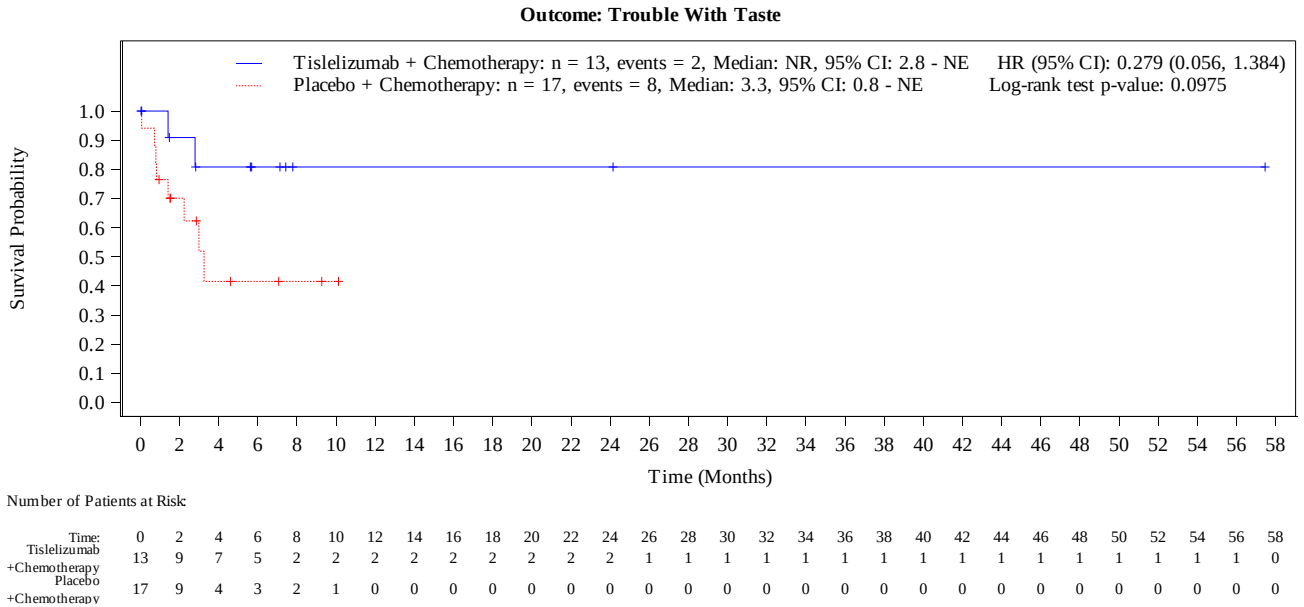

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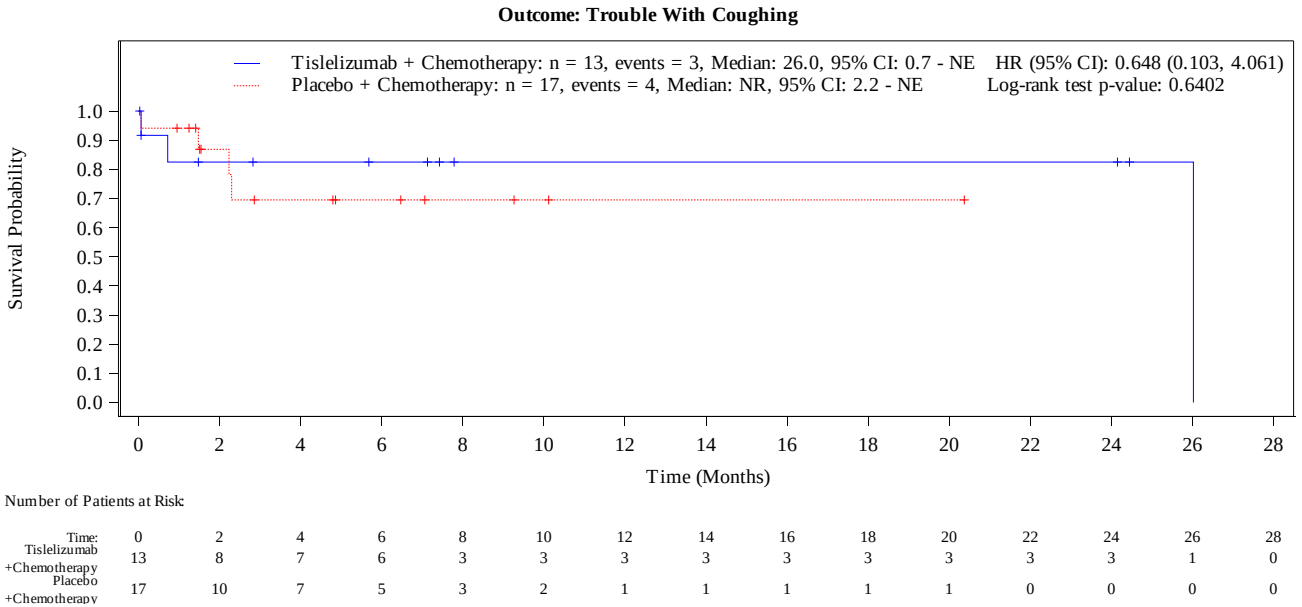

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ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

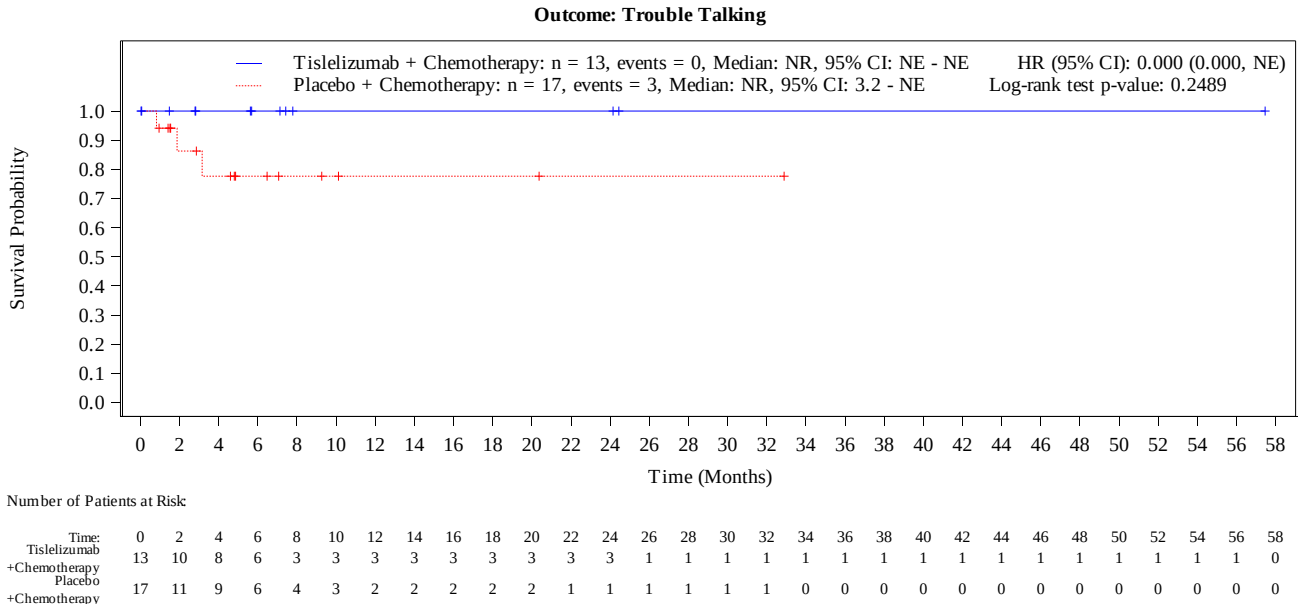

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	5 (55.6)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	4 (36.4)	--	--	--
Female	4	3 (75.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dysphagia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	2 (20.0)	--	--	--
1	6	3 (50.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	3 (42.9)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Eating

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	0 (0.0)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	1 (25.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Reflux

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	2 (18.2)	--	--	--
Female	4	1 (25.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Pain

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	5 (45.5)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Swallowing Saliva

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	1 (11.1)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Choked When Swallowing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	4 (57.1)	--	--	--
No	9	1 (11.1)	--	10	1 (10.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	5 (62.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	5 (45.5)	--	--	--
Female	4	1 (25.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Dry Mouth

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	5 (71.4)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	5 (71.4)	--	--	--
No	9	2 (22.2)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	5 (55.6)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Taste

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	4 (57.1)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	1 (11.1)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble With Coughing

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	2 (20.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: Trouble Talking

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	2 (20.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	3 (42.9)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

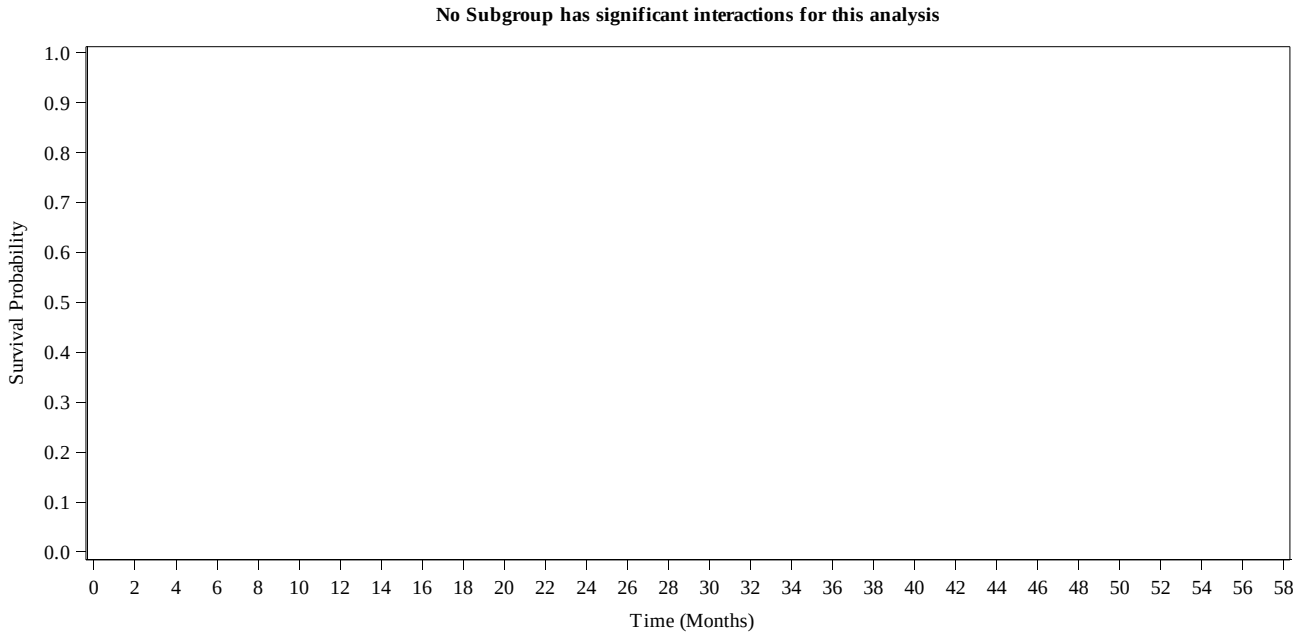
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 14NOV2024 06:33 t-14-2-6-3-1-2-s-eff-tteqs-subgrp-oes-pop1-cl.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 14NOV2024 06:23 f-14-2-7-2-2-s-km-tteqs-subgrp-oes-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	12		17	
	Mean (SD)	70.6 (26.11)		64.8 (19.76)	
	Median	77.0		69.0	
	Q1, Q3	51.0, 90.0		51.0, 80.0	
	Min, Max	13, 98		20, 92	
Cycle 2	n	10	10	15	15
	Mean (SD)	77.7 (17.80)	7.4 (29.15)	67.8 (19.24)	3.7 (15.57)
	Median	80.0	2.0	75.0	5.0
	Q1, Q3	76.0, 89.0	-10.0, 13.0	61.0, 80.0	-9.0, 15.0
	Min, Max	40, 98	-39, 63	20, 88	-23, 28
Cycle 3	n	10	10	12	12
	Mean (SD)	79.2 (12.62)	8.9 (20.30)	69.1 (23.00)	2.5 (20.25)
	Median	81.0	6.0	75.5	2.0
	Q1, Q3	69.0, 90.0	-8.0, 15.0	65.0, 84.0	-9.5, 19.5
	Min, Max	59, 95	-10, 47	20, 95	-33, 27

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	9	9	12	12
	Mean (SD)	78.4 (18.41)	9.1 (16.47)	65.8 (22.06)	-0.8 (20.74)
	Median	80.0	8.0	75.0	-0.5
	Q1, Q3	79.0, 92.0	-3.0, 17.0	55.0, 80.0	-17.5, 16.0
	Min, Max	39, 96	-11, 39	21, 91	-31, 35
Cycle 5	n	8	8	11	11
	Mean (SD)	80.9 (14.97)	9.4 (17.34)	72.0 (16.73)	3.9 (20.78)
	Median	85.0	9.0	75.0	4.0
	Q1, Q3	74.5, 90.0	-6.5, 22.0	70.0, 80.0	-10.0, 23.0
	Min, Max	50, 98	-11, 37	31, 100	-30, 35
Cycle 6	n	8	8	9	9
	Mean (SD)	79.9 (16.00)	8.4 (16.29)	73.0 (19.69)	1.9 (22.62)
	Median	84.0	8.5	76.0	0.0
	Q1, Q3	72.5, 90.5	-7.5, 20.0	70.0, 80.0	-12.0, 24.0
	Min, Max	48, 97	-10, 35	27, 100	-34, 31

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 8	n	7	7	7	7
	Mean (SD)	80.6 (19.26)	9.6 (15.74)	81.3 (9.23)	6.0 (16.64)
	Median	87.0	5.0	80.0	0.0
	Q1, Q3	75.0, 95.0	-3.0, 27.0	79.0, 81.0	-9.0, 20.0
	Min, Max	40, 95	-8, 34	69, 100	-12, 35
Cycle 10	n	4	4	6	6
	Mean (SD)	79.0 (27.22)	18.5 (18.16)	78.7 (15.33)	4.2 (22.66)
	Median	88.0	16.0	80.0	4.0
	Q1, Q3	60.5, 97.5	3.5, 33.5	79.0, 81.0	-10.0, 21.0
	Min, Max	40, 100	2, 40	52, 100	-29, 35
Cycle 12	n	3	3	5	5
	Mean (SD)	63.7 (25.11)	13.0 (18.52)	79.0 (13.06)	8.0 (24.58)
	Median	61.0	20.0	79.0	7.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	75.0, 86.0	-11.0, 30.0
	Min, Max	40, 90	-8, 27	60, 95	-21, 35

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 14	n	3	3	3	3
	Mean (SD)	77.7 (22.23)	27.0 (30.81)	76.3 (6.35)	3.0 (16.09)
	Median	90.0	39.0	80.0	1.0
	Q1, Q3	52.0, 91.0	-8.0, 50.0	69.0, 80.0	-12.0, 20.0
	Min, Max	52, 91	-8, 50	69, 80	-12, 20
Cycle 16	n	3	3	2	2
	Mean (SD)	71.0 (19.00)	20.3 (24.95)	74.0 (7.07)	-11.5 (0.71)
	Median	71.0	30.0	74.0	-11.5
	Q1, Q3	52.0, 90.0	-8.0, 39.0	69.0, 79.0	-12.0, -11.0
	Min, Max	52, 90	-8, 39	69, 79	-12, -11
Cycle 18	n	3	3	3	3
	Mean (SD)	63.3 (25.17)	12.7 (18.34)	76.7 (5.77)	-6.7 (6.66)
	Median	60.0	19.0	80.0	-10.0
	Q1, Q3	40.0, 90.0	-8.0, 27.0	70.0, 80.0	-11.0, 1.0
	Min, Max	40, 90	-8, 27	70, 80	-11, 1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 20	n	3	3	3	3
	Mean (SD)	75.0 (21.79)	24.3 (28.22)	80.3 (0.58)	-3.0 (6.08)
	Median	85.0	37.0	80.0	0.0
	Q1, Q3	50.0, 90.0	-8.0, 44.0	80.0, 81.0	-10.0, 1.0
	Min, Max	50, 90	-8, 44	80, 81	-10, 1
Cycle 22	n	3	3	3	3
	Mean (SD)	70.3 (30.01)	19.7 (15.37)	76.3 (7.23)	-7.0 (13.08)
	Median	71.0	27.0	80.0	-1.0
	Q1, Q3	40.0, 100.0	2.0, 30.0	68.0, 81.0	-22.0, 2.0
	Min, Max	40, 100	2, 30	68, 81	-22, 2
Cycle 24	n	2	2	3	3
	Mean (SD)	86.0 (7.07)	16.5 (33.23)	78.0 (7.21)	-5.3 (13.05)
	Median	86.0	16.5	80.0	-1.0
	Q1, Q3	81.0, 91.0	-7.0, 40.0	70.0, 84.0	-20.0, 5.0
	Min, Max	81, 91	-7, 40	70, 84	-20, 5

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 26	n	3	3	3	3
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	81.7 (3.79)	-1.7 (2.52)
	Median	71.0	30.0	80.0	-2.0
	Q1, Q3	50.0, 90.0	-8.0, 37.0	79.0, 86.0	-4.0, 1.0
	Min, Max	50, 90	-8, 37	79, 86	-4, 1
Cycle 28	n	3	3	2	2
	Mean (SD)	70.3 (20.01)	19.7 (24.21)	80.5 (13.44)	-5.0 (19.80)
	Median	71.0	30.0	80.5	-5.0
	Q1, Q3	50.0, 90.0	-8.0, 37.0	71.0, 90.0	-19.0, 9.0
	Min, Max	50, 90	-8, 37	71, 90	-19, 9
Cycle 30	n	2	2	2	2
	Mean (SD)	65.5 (21.92)	38.5 (2.12)	79.5 (0.71)	-6.0 (7.07)
	Median	65.5	38.5	79.5	-6.0
	Q1, Q3	50.0, 81.0	37.0, 40.0	79.0, 80.0	-11.0, -1.0
	Min, Max	50, 81	37, 40	79, 80	-11, -1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 32	n	3	3	1	1
	Mean (SD)	74.3 (20.60)	23.7 (27.47)	81.0 (NE)	-9.0 (NE)
	Median	82.0	38.0	81.0	-9.0
	Q1, Q3	51.0, 90.0	-8.0, 41.0	81.0, 81.0	-9.0, -9.0
	Min, Max	51, 90	-8, 41	81, 81	-9, -9
Cycle 34	n	3	3	1	1
	Mean (SD)	76.3 (25.70)	25.7 (20.55)	87.0 (NE)	-3.0 (NE)
	Median	80.0	36.0	87.0	-3.0
	Q1, Q3	49.0, 100.0	2.0, 39.0	87.0, 87.0	-3.0, -3.0
	Min, Max	49, 100	2, 39	87, 87	-3, -3
Cycle 36	n	2	2	1	1
	Mean (SD)	69.5 (28.99)	14.0 (31.11)	70.0 (NE)	-20.0 (NE)
	Median	69.5	14.0	70.0	-20.0
	Q1, Q3	49.0, 90.0	-8.0, 36.0	70.0, 70.0	-20.0, -20.0
	Min, Max	49, 90	-8, 36	70, 70	-20, -20

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 38	n	1	1	1	1
	Mean (SD)	48.0 (NE)	35.0 (NE)	95.0 (NE)	5.0 (NE)
	Median	48.0	35.0	95.0	5.0
	Q1, Q3	48.0, 48.0	35.0, 35.0	95.0, 95.0	5.0, 5.0
	Min, Max	48, 48	35, 35	95, 95	5, 5
Cycle 40	n	0	0	1	1
	Mean (SD)			70.0 (NE)	-20.0 (NE)
	Median			70.0	-20.0
	Q1, Q3			70.0, 70.0	-20.0, -20.0
	Min, Max			70, 70	-20, -20
Cycle 42	n	1	1	1	1
	Mean (SD)	54.0 (NE)	41.0 (NE)	70.0 (NE)	-20.0 (NE)
	Median	54.0	41.0	70.0	-20.0
	Q1, Q3	54.0, 54.0	41.0, 41.0	70.0, 70.0	-20.0, -20.0
	Min, Max	54, 54	41, 41	70, 70	-20, -20

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 44	n	1	1	1	1
	Mean (SD)	48.0 (NE)	35.0 (NE)	65.0 (NE)	-25.0 (NE)
	Median	48.0	35.0	65.0	-25.0
	Q1, Q3	48.0, 48.0	35.0, 35.0	65.0, 65.0	-25.0, -25.0
	Min, Max	48, 48	35, 35	65, 65	-25, -25
Cycle 46	n	1	1	1	1
	Mean (SD)	40.0 (NE)	27.0 (NE)	55.0 (NE)	-35.0 (NE)
	Median	40.0	27.0	55.0	-35.0
	Q1, Q3	40.0, 40.0	27.0, 27.0	55.0, 55.0	-35.0, -35.0
	Min, Max	40, 40	27, 27	55, 55	-35, -35
Cycle 48	n	1	1	0	0
	Mean (SD)	60.0 (NE)	47.0 (NE)		
	Median	60.0	47.0		
	Q1, Q3	60.0, 60.0	47.0, 47.0		
	Min, Max	60, 60	47, 47		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 50	n	1	1	0	0
	Mean (SD)	48.0 (NE)	35.0 (NE)		
	Median	48.0	35.0		
	Q1, Q3	48.0, 48.0	35.0, 35.0		
	Min, Max	48, 48	35, 35		
Cycle 52	n	1	1	0	0
	Mean (SD)	58.0 (NE)	45.0 (NE)		
	Median	58.0	45.0		
	Q1, Q3	58.0, 58.0	45.0, 45.0		
	Min, Max	58, 58	45, 45		
Cycle 54	n	1	1	0	0
	Mean (SD)	51.0 (NE)	38.0 (NE)		
	Median	51.0	38.0		
	Q1, Q3	51.0, 51.0	38.0, 38.0		
	Min, Max	51, 51	38, 38		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 56	n	1	1	0	0
	Mean (SD)	70.0 (NE)	57.0 (NE)		
	Median	70.0	57.0		
	Q1, Q3	70.0, 70.0	57.0, 57.0		
	Min, Max	70, 70	57, 57		
Cycle 58	n	1	1	0	0
	Mean (SD)	44.0 (NE)	31.0 (NE)		
	Median	44.0	31.0		
	Q1, Q3	44.0, 44.0	31.0, 31.0		
	Min, Max	44, 44	31, 31		
Cycle 60	n	1	1	0	0
	Mean (SD)	66.0 (NE)	53.0 (NE)		
	Median	66.0	53.0		
	Q1, Q3	66.0, 66.0	53.0, 53.0		
	Min, Max	66, 66	53, 53		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 62	n	1	1	0	0
	Mean (SD)	60.0 (NE)	47.0 (NE)		
	Median	60.0	47.0		
	Q1, Q3	60.0, 60.0	47.0, 47.0		
	Min, Max	60, 60	47, 47		
Cycle 64	n	1	1	0	0
	Mean (SD)	52.0 (NE)	39.0 (NE)		
	Median	52.0	39.0		
	Q1, Q3	52.0, 52.0	39.0, 39.0		
	Min, Max	52, 52	39, 39		
Cycle 66	n	1	1	0	0
	Mean (SD)	45.0 (NE)	32.0 (NE)		
	Median	45.0	32.0		
	Q1, Q3	45.0, 45.0	32.0, 32.0		
	Min, Max	45, 45	32, 32		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 68	n	1	1	0	0
	Mean (SD)	49.0 (NE)	36.0 (NE)		
	Median	49.0	36.0		
	Q1, Q3	49.0, 49.0	36.0, 36.0		
	Min, Max	49, 49	36, 36		
Cycle 70	n	1	1	0	0
	Mean (SD)	47.0 (NE)	34.0 (NE)		
	Median	47.0	34.0		
	Q1, Q3	47.0, 47.0	34.0, 34.0		
	Min, Max	47, 47	34, 34		
Cycle 72	n	1	1	0	0
	Mean (SD)	29.0 (NE)	16.0 (NE)		
	Median	29.0	16.0		
	Q1, Q3	29.0, 29.0	16.0, 16.0		
	Min, Max	29, 29	16, 16		

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Parameter: EQ VAS Score

		Tislelizumab + Chemotherapy (N = 13)		Placebo + Chemotherapy (N = 17)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
End of Treatment	n	10	10	16	16
	Mean (SD)	66.8 (24.58)	-3.1 (33.83)	63.8 (24.73)	-2.6 (17.47)
	Median	72.0	-4.0	70.0	-1.5
	Q1, Q3	59.0, 82.0	-13.0, 15.0	50.0, 76.5	-12.0, 9.5
	Min, Max	10, 94	-80, 41	10, 100	-40, 25
Worst Post-Baseline Value	n	12	12	17	17
	Mean (SD)	58.6 (26.61)	-12.0 (25.12)	54.7 (19.95)	-10.1 (18.17)
	Median	60.5	-8.0	60.0	-3.0
	Q1, Q3	40.0, 80.0	-11.5, 1.0	49.0, 67.0	-26.0, 2.0
	Min, Max	10, 94	-80, 16	10, 85	-40, 15

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
For patients whose Cycle 1 questionnaires were completed on or before randomization date, Cycle 1 is considered the Baseline visit; otherwise, the Screening is considered the Baseline visit.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-qs-chg.sas 26NOV2024 21:35 t-14-2-6-5-1-qs-chg-eq5d-pop1-cl.rtf

Table 14.2.6.5.1.1:
EQ-5D-VAS: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
EQ-5D VAS									
Cycle 6	8		--	9		--	--	--	--
Cycle 8	7		--	7		--	--	--	--
Overall Treatment Effect	11	70.58 (26.11)	5.88 (4.76)	17	64.76 (19.76)	3.75 (3.66)	2.13 (-8.79, 13.05)	0.17 (-0.68, 1.01)	0.6902

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Only patients with baseline and postbaseline value are included in analysis. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

The mixed effect model only includes visits where both arms have at least 10 patients. All subsequent visits after the first visit with less than 10 patients in one or two arms will be excluded in the modelling. Total number of patients will be displayed.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as covariates, and an AR(1) covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab+chemotherapy arm minus that of placebo+ chemotherapy arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-mmrmqs.sas 14NOV2024 02:07 t-14-2-6-5-1-1-eff-mmrmqs-vas-pop1-cl.rtf

Table 14.2.6.5.1.2:
Analyses of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	13	1 (7.7)	NR (NE, NE)	17	4 (23.5)	14.7 (3.2, NE)	0.636 (0.066, 6.122)	0.6928

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: NE = not estimable; NR = not reached

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

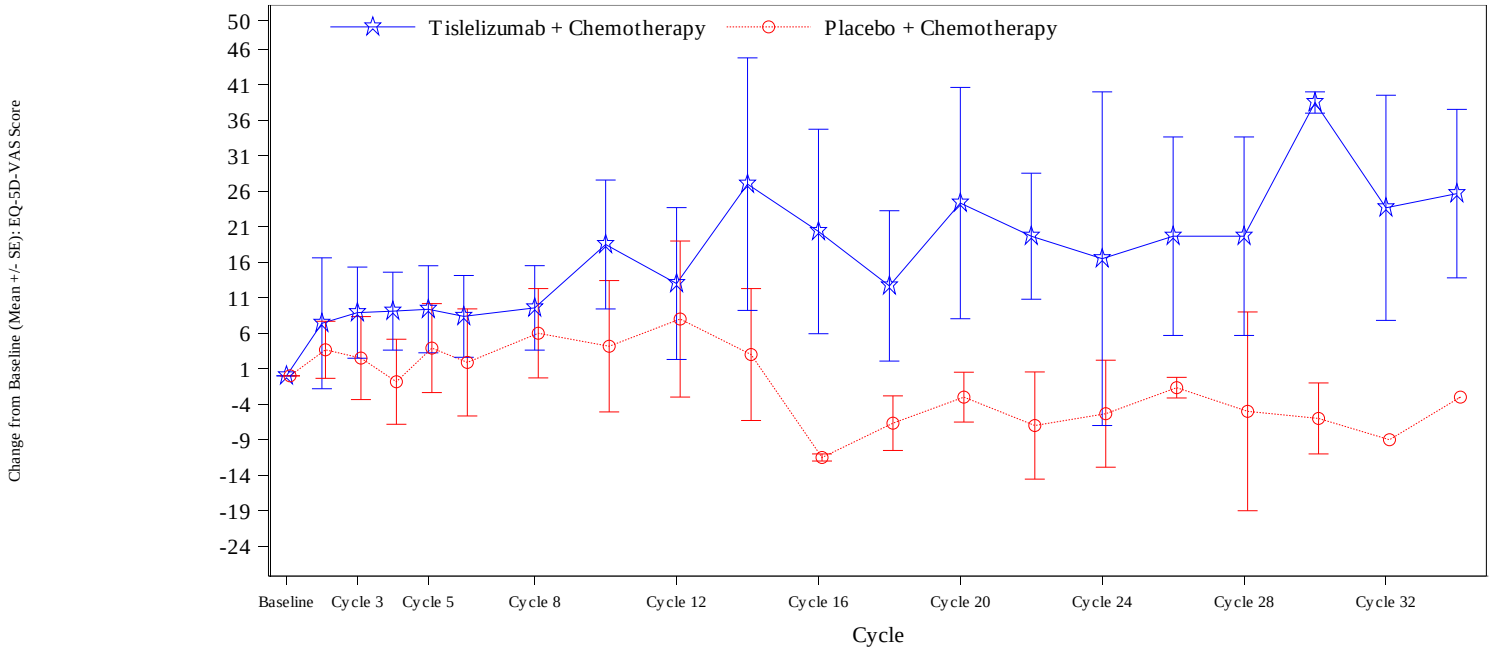
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-eff-tte-qlq.sas 14NOV2024 06:32 t-14-2-6-5-1-2-eff-tte-qlq-vas-pop1-cl.rtf

Figure 14.2.7.4:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

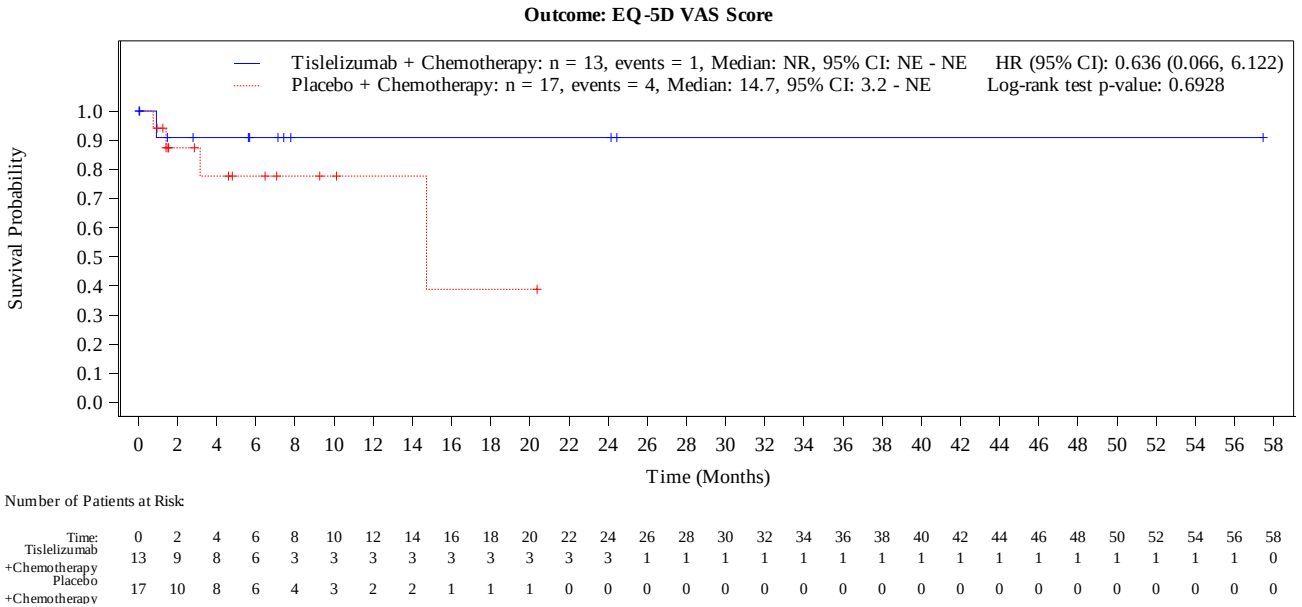


No. of Patients

Tislelizumab + Chemotherapy	12	10	10	9	8	8	7	4	3	3	3	3	3	3	2	3	3	2	3	3
Placebo + Chemotherapy	17	15	12	12	11	9	7	6	5	3	2	3	3	3	3	3	2	2	1	1

Source: ADQS. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-series.sas 26NOV2024 21:27 f-14-2-7-4-series-eq5d-pop1-cl.rtf

Figure 14.2.7.4.2:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-qs.sas 14NOV2024 05:56 f-14-2-7-4-2-km-qs-vas-pop1-cl.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	1 (12.5)	--	--	--
Age >= 65	4	1 (25.0)	--	9	3 (33.3)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Outcome: EQ-5D VAS Score

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	0 (0.0)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	4 (57.1)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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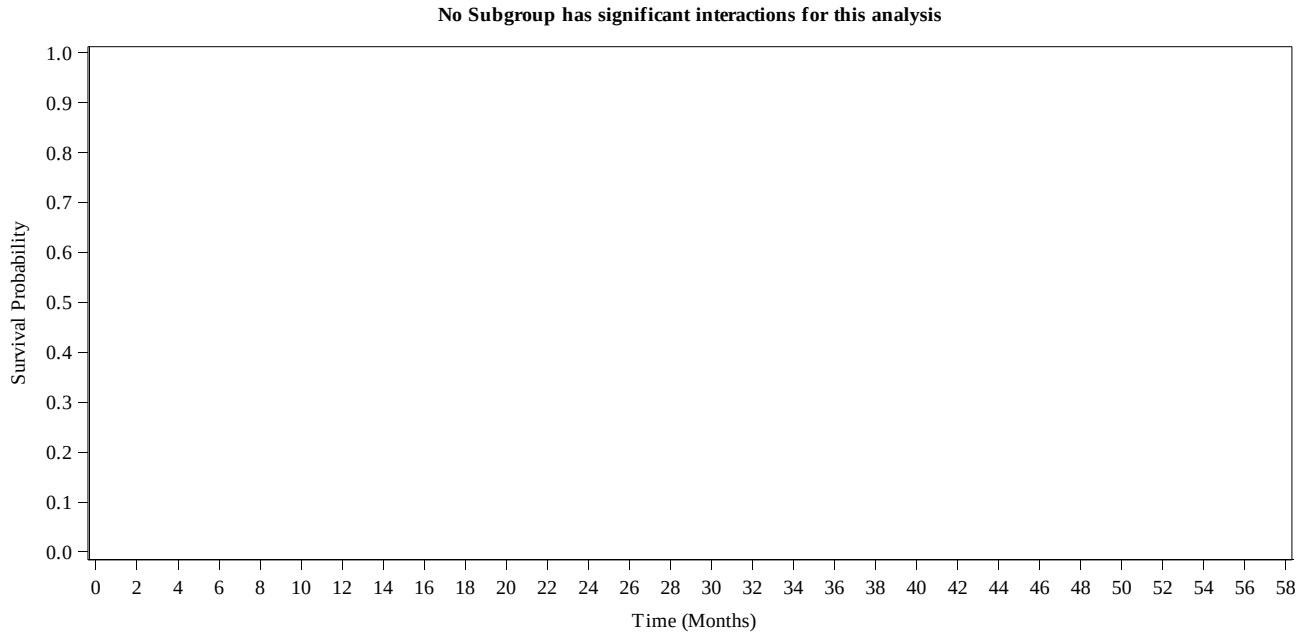
Figure 14.2.7.4.2.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEQS1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 14NOV2024 06:23 f-14-2-7-4-2-s-km-tteqs-subgrp-vas-pop1-cl.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Patients with Any Subsequent Anti-Cancer Therapy, n (%)	10 (76.9)	13 (76.5)
Radiotherapy	2 (15.4)	6 (35.3)
Procedure or Surgery	1 (7.7)	2 (11.8)
Systemic Therapy	10 (76.9)	12 (70.6)
Immunotherapy	5 (38.5)	7 (41.2)
Time to First Post-Treatment Anti-Cancer Therapy (months)		
n	10	13
Mean (SD)	4.08 (6.616)	2.05 (2.757)
Median	1.12	1.61
Q1, Q3	0.79, 4.27	0.56, 2.07
Min, Max	0.6, 22.1	0.3, 10.8

Source: ADCM, ADPR, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.
Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-byanti.sas 14NOV2024 06:39 t-14-2-8-1-byanti-pop1-cl.rtf

Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Time to First Post-Treatment Immunotherapy (months)		
n	5	7
Mean (SD)	8.38 (9.054)	2.70 (2.322)
Median	6.11	2.63
Q1, Q3	0.79, 12.25	0.56, 4.27
Min, Max	0.6, 22.1	0.3, 6.8
Post-Treatment Anti-Cancer Therapy Duration (months)		
Systemic Therapy		
n	10	12
Mean (SD)	10.62 (8.248)	6.15 (8.915)
Median	10.32	2.99
Q1, Q3	3.71, 15.41	0.92, 7.56
Min, Max	1.1, 25.1	0.0, 31.6
Patients with Ongoing Anti-Cancer Systemic Therapy at Data Cutoff, n (%)	0 (0.0)	0 (0.0)

Source: ADCM, ADPR, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Percentages were based on N.

Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.

Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.2.8.1:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)	Placebo + Chemotherapy (N = 17)
Immunotherapy		
n	5	7
Mean (SD)	1.94 (1.782)	3.10 (3.619)
Median	1.12	1.64
Q1, Q3	1.05, 1.77	0.03, 7.62
Min, Max	0.7, 5.1	0.0, 8.9
Patients with Ongoing Immunotherapy at Data Cutoff, n (%)	0 (0.0)	0 (0.0)

Source: ADCM, ADPR, ADBASE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Percentages were based on N.

Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from last dose of all study treatments to first dose of subsequent anti-cancer therapy.

Time to first subsequent immunotherapy is defined for patients with the use of subsequent immunotherapy as the time from last dose of all study treatments to first dose of subsequent immunotherapy.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-byanti.sas 14NOV2024 06:39 t-14-2-8-1-byanti-pop1-cl.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Duration of Treatment (month) [a]			
n	13	17	30
Mean (SD)	13.58 (16.731)	7.58 (8.796)	10.18 (12.949)
Median	5.65	4.14	5.22
Q1, Q3	2.76, 24.11	1.58, 8.77	2.53, 10.25
Min, Max	0.7, 57.2	0.7, 32.6	0.7, 57.2
Duration of Treatment, n (%)			
< 1 month	2 (15.4)	2 (11.8)	4 (13.3)
≥ 1 to < 3 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 3 to < 6 months	3 (23.1)	4 (23.5)	7 (23.3)
≥ 6 to < 12 months	2 (15.4)	4 (23.5)	6 (20.0)
≥ 12 to < 18 months	0 (0.0)	0 (0.0)	0 (0.0)
≥ 18 to < 24 months	0 (0.0)	2 (11.8)	2 (6.7)
≥ 24 months	4 (30.8)	1 (5.9)	5 (16.7)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date) - first dose date + 1)/30.4375, if patients discontinued from treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:34 t-14-3-1-1-1-ex-tis-pop1-cl.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Number of Cycles Received			
n	13	17	30
Mean (SD)	18.0 (21.52)	9.4 (10.85)	13.1 (16.60)
Median	8.0	5.0	7.5
Q1, Q3	4.0, 34.0	2.0, 12.0	3.0, 14.0
Min, Max	1, 72	1, 42	1, 72
Number of Cycles Received, n (%)			
1-3	3 (23.1)	7 (41.2)	10 (33.3)
4-6	1 (7.7)	3 (17.6)	4 (13.3)
7-9	4 (30.8)	1 (5.9)	5 (16.7)
10-12	1 (7.7)	2 (11.8)	3 (10.0)
13-18	0 (0.0)	2 (11.8)	2 (6.7)
19-24	0 (0.0)	0 (0.0)	0 (0.0)
25-36	2 (15.4)	1 (5.9)	3 (10.0)
>36	2 (15.4)	1 (5.9)	3 (10.0)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date) - first dose date + 1)/30.4375, if patients discontinued from treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:34 t-14-3-1-1-1-ex-tis-pop1-cl.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Cumulative Total Dose (mg) per Patient [b]			
n	13	17	30
Mean (SD)	3600.00 (4303.487)	1870.59 (2170.186)	2620.00 (3319.888)
Median	1600.00	1000.00	1500.00
Q1, Q3	800.00, 6800.00	400.00, 2400.00	600.00, 2800.00
Min, Max	200.0, 14400.0	200.0, 8400.0	200.0, 14400.0
Actual Dose Intensity (mg/cycle) per Patient [c]			
n	13	17	30
Mean (SD)	187.80 (14.353)	178.05 (26.275)	182.28 (22.142)
Median	194.92	186.67	188.61
Q1, Q3	174.19, 198.82	171.43, 198.11	173.59, 198.82
Min, Max	161.5, 200.0	112.4, 200.0	112.4, 200.0

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date) - first dose date + 1)/30.4375, if patients discontinued from treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:34 t-14-3-1-1-1-ex-tis-pop1-cl.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Relative Dose Intensity (%) per Patient [d]			
n	13	17	30
Mean (SD)	93.90 (7.177)	89.03 (13.137)	91.14 (11.071)
Median	97.46	93.33	94.31
Q1, Q3	87.10, 99.41	85.71, 99.06	86.80, 99.41
Min, Max	80.8, 100.0	56.2, 100.0	56.2, 100.0
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	2 (11.8)	2 (6.7)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date) - first dose date + 1)/30.4375, if patients discontinued from treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:34 t-14-3-1-1-1-ex-tis-pop1-cl.rtf

Table 14.3.1.1.1:
Study Medication Administration - Tislelizumab/Placebo
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab (N = 13)	Placebo (N = 17)	Total (N = 30)
Patients with Any Dose Modification, n (%)	8 (61.5)	11 (64.7)	19 (63.3)
Dose Delay	8 (61.5)	11 (64.7)	19 (63.3)
Adverse Event	3 (23.1)	10 (58.8)	13 (43.3)
Other	7 (53.8)	4 (23.5)	11 (36.7)
Related to COVID-19	2 (15.4)	2 (11.8)	4 (13.3)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	0 (0.0)	0 (0.0)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value. Percentages were based on N.
[a] Duration of treatment = (min(last dose date + 20, death date) - first dose date + 1)/30.4375, if patients discontinued from treatment.
[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient.
[c] Actual Dose Intensity is 21*cumulative total dose (mg) / (last dose date+ 21 - first dose date).
[d] Relative Dose Intensity is actual dose intensity / (200 mg/cycle).
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-ex-tis.sas 14NOV2024 00:34 t-14-3-1-1-1-ex-tis-pop1-cl.rtf

Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment (month) [a]				
n	13	13	17	17
Mean (SD)	4.12 (2.138)	7.21 (11.051)	3.51 (1.918)	5.08 (5.151)
Median	4.27	4.30	3.48	4.17
Q1, Q3	2.76, 4.90	2.79, 6.87	1.68, 4.40	1.71, 6.14
Min, Max	0.7, 8.3	0.7, 43.3	0.7, 7.2	0.7, 22.4

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Duration of Treatment, n (%)				
< 1 month	2 (15.4)	2 (15.4)	2 (11.8)	2 (11.8)
≥ 1 to < 3 months	2 (15.4)	2 (15.4)	4 (23.5)	4 (23.5)
≥ 3 to < 6 months	7 (53.8)	5 (38.5)	9 (52.9)	6 (35.3)
≥ 6 to < 12 months	2 (15.4)	3 (23.1)	2 (11.8)	4 (23.5)
≥ 12 to ≤ 18 months	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
> 18 months	0 (0.0)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received				
n	13	13	17	17
Mean (SD)	5.5 (2.67)	9.1 (12.89)	4.5 (2.45)	5.9 (4.55)
Median	6.0	6.0	5.0	5.0
Q1, Q3	4.0, 6.0	4.0, 8.0	2.0, 6.0	2.0, 8.0
Min, Max	1, 10	1, 51	1, 9	1, 17

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Number of Cycles Received, n (%)				
1-3	3 (23.1)	3 (23.1)	7 (41.2)	7 (41.2)
4-6	7 (53.8)	5 (38.5)	7 (41.2)	4 (23.5)
7-9	2 (15.4)	3 (23.1)	3 (17.6)	3 (17.6)
10-12	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)
13-18	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
>18	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Cumulative Total Dose (mg/m^2) per Patient [b]				
n	13	13	17	17
Mean (SD)	356.59 (173.633)	35771.80 (53377.563)	289.96 (155.327)	21636.25 (17662.020)
Median	359.07	22461.80	296.93	19909.72
Q1, Q3	276.36, 451.08	16162.38, 31793.25	164.68, 402.36	8162.99, 26944.39
Min, Max	71.9, 648.8	3671.0, 209891.7	59.9, 556.6	3749.5, 68382.0

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Actual Dose Intensity (mg/m^2/cycle) per Patient [c]				
n	13	13	17	17
Mean (SD)	62.39 (12.288)	3512.76 (363.810)	59.38 (12.483)	3169.15 (642.132)
Median	59.84	3504.12	58.30	3485.46
Q1, Q3	53.85, 73.42	3344.25, 3712.21	50.12, 67.03	2710.97, 3665.54
Min, Max	38.2, 80.6	2695.7, 3993.1	41.3, 82.3	2102.5, 3986.6

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Relative Dose Intensity (%) per Patient [d]				
n	13	13	17	17
Mean (SD)	87.64 (16.755)	90.53 (9.771)	82.39 (16.600)	79.75 (16.536)
Median	96.97	93.44	84.41	78.65
Q1, Q3	84.77, 99.22	83.86, 98.68	68.89, 97.17	67.77, 95.44
Min, Max	47.7, 100.7	67.4, 99.8	54.2, 102.9	52.6, 99.7
Number of Patients Treated beyond Investigator Assessed Radiological Progression, n (%)	0 (0.0)	0 (0.0)	1 (5.9)	2 (11.8)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Patients with Any Dose Modification, n (%)	7 (53.8)	8 (61.5)	12 (70.6)	14 (82.4)
Dose Delay	7 (53.8)	7 (53.8)	9 (52.9)	10 (58.8)
Adverse Event	5 (38.5)	4 (30.8)	8 (47.1)	8 (47.1)
Other	3 (23.1)	5 (38.5)	1 (5.9)	3 (17.6)
Related to COVID-19	1 (7.7)	1 (7.7)	0 (0.0)	1 (5.9)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.1.2:
Study Medication Administration - Chemotherapy Doublet A
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy N = 13		Placebo + Chemotherapy N = 17	
	Cisplatin + 5-FU N = 13		Cisplatin + 5-FU N = 17	
	Cisplatin (m = 13)	5-FU (m = 13)	Cisplatin (m = 17)	5-FU (m = 17)
Infusion Interruption/Infusion Rate Decrease	0 (0.0)	3 (23.1)	0 (0.0)	7 (41.2)
Adverse Event	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
Other	0 (0.0)	3 (23.1)	0 (0.0)	6 (35.3)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dose Reduction	4 (30.8)	2 (15.4)	11 (64.7)	8 (47.1)
Adverse Event	4 (30.8)	2 (15.4)	9 (52.9)	8 (47.1)
Other	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile; Min, minimum value; Max, maximum value.Percentages were based on m. m = number of patients taking at least one dose of chemotherapy agent under corresponding column.

[a] Duration of treatment (TD) for patients discontinued from treatment: For cisplatin on a Q3W schedule, TD = (min(last dose date + 20, death date) - first dose date + 1)/30.4375; For 5-FU, TD = (min(last dose date + 16, death date) - first dose date + 1)/30.4375.

[b] Cumulative Total Dose per patient is the sum of actual received doses of all visits per patient for each study drug.

[c] Actual Dose Intensity is max((last dose date + 21 - first dose date)/21, number of cycles in last CRF page) for cisplatin; max((last dose date + 17- first dose date)/21, number of cycles in last CRF page) for 5-FU.

[d] Relative Dose Intensity is actual dose intensity/planned dose intensity. The planned dose intensity is the total planned dose in first cycle.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-ex-chemo.sas 14NOV2024 00:33 t-14-3-1-1-2-ex-chemo-a-pop1-cl.rtf

Table 14.3.1.2.1.1:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	13	13 (100.0)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.1)	0.420 (0.145, 1.218)	0.1047
TEAE >= Grade 3	13	10 (76.9)	0.9 (0.2, 7.1)	17	14 (82.4)	1.0 (0.2, 2.1)	0.936 (0.313, 2.795)	0.9373
Serious TEAE	13	4 (30.8)	NR (5.0, NE)	17	6 (35.3)	20.5 (0.3, NE)	1.033 (0.245, 4.359)	0.9650
TEAE Leading to Treatment Discontinuation	13	2 (15.4)	NR (NE, NE)	17	6 (35.3)	NR (3.9, NE)	1.071 (0.177, 6.472)	0.9406

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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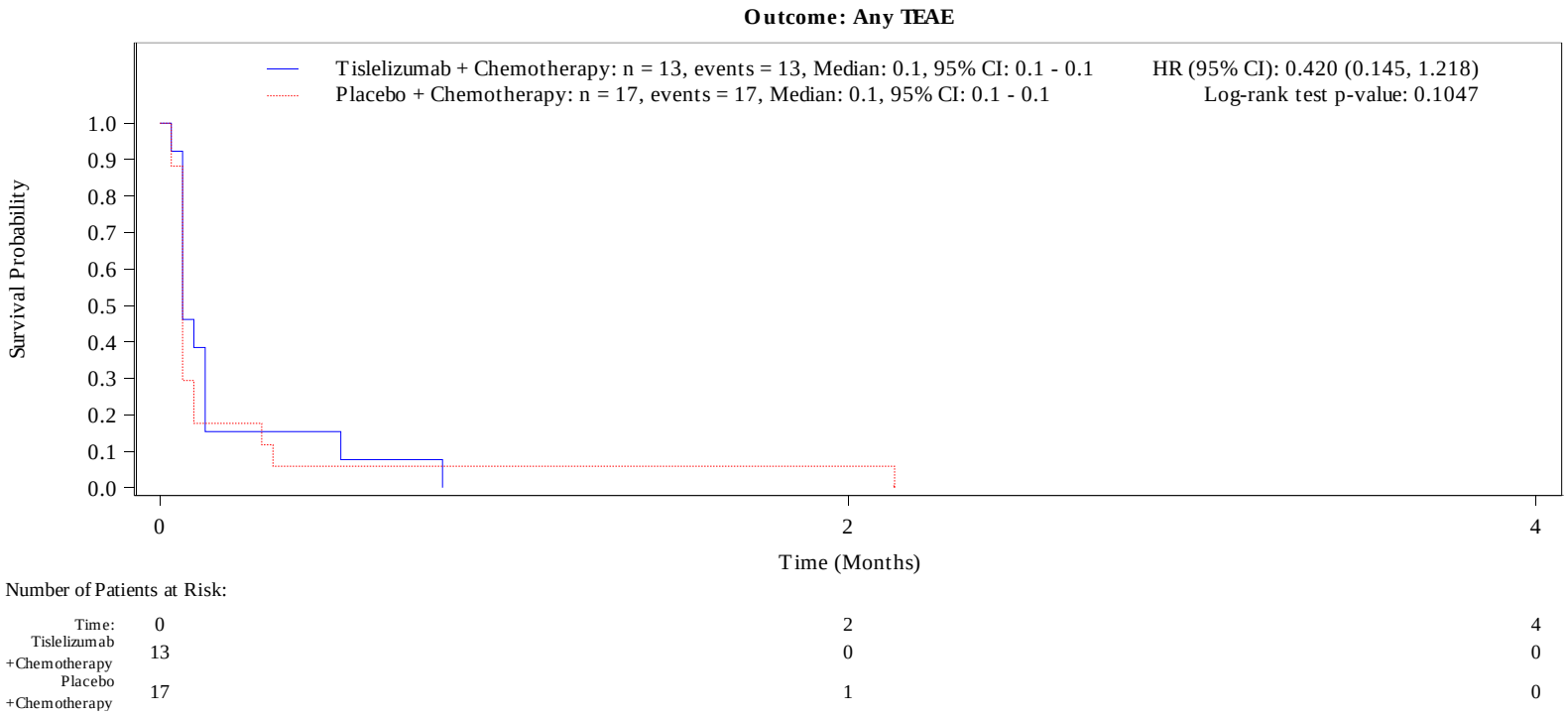
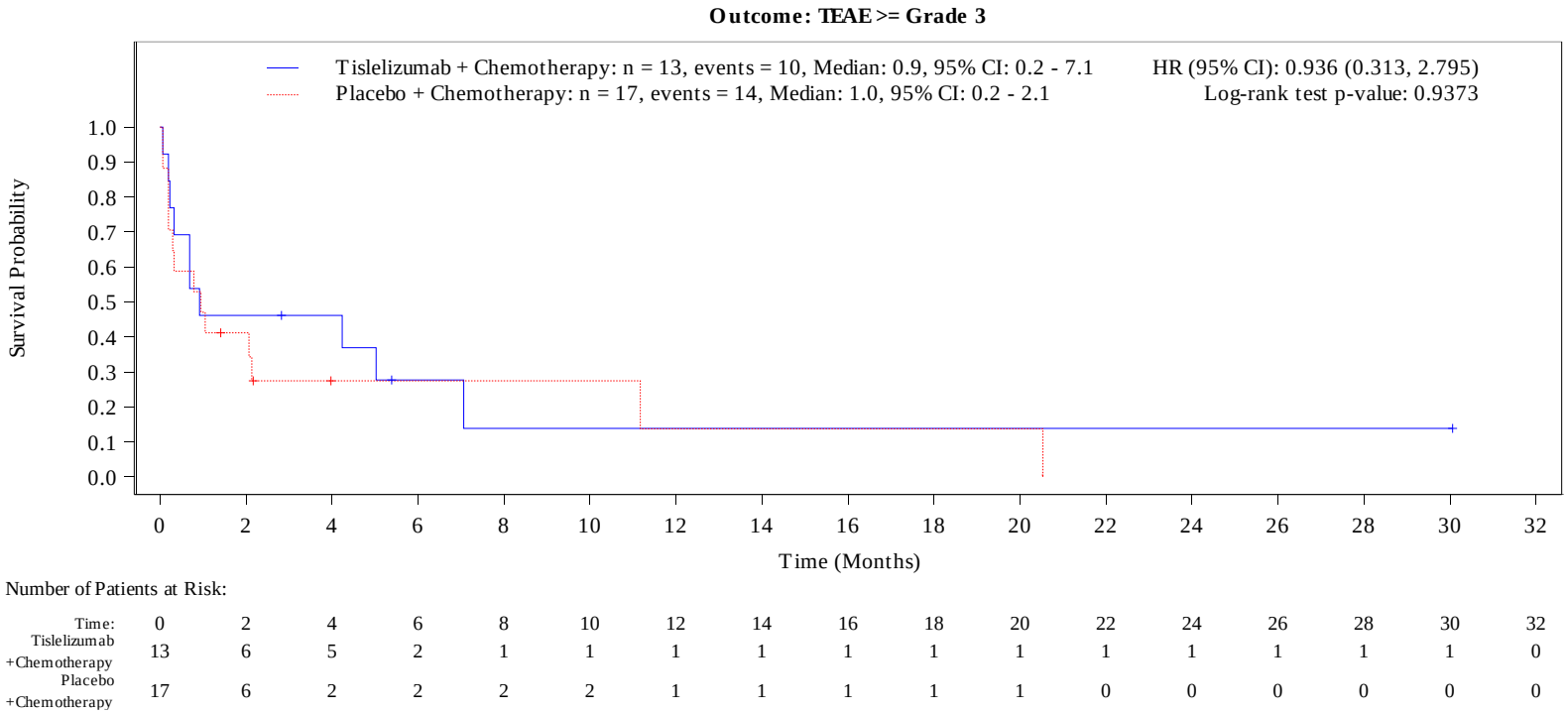
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



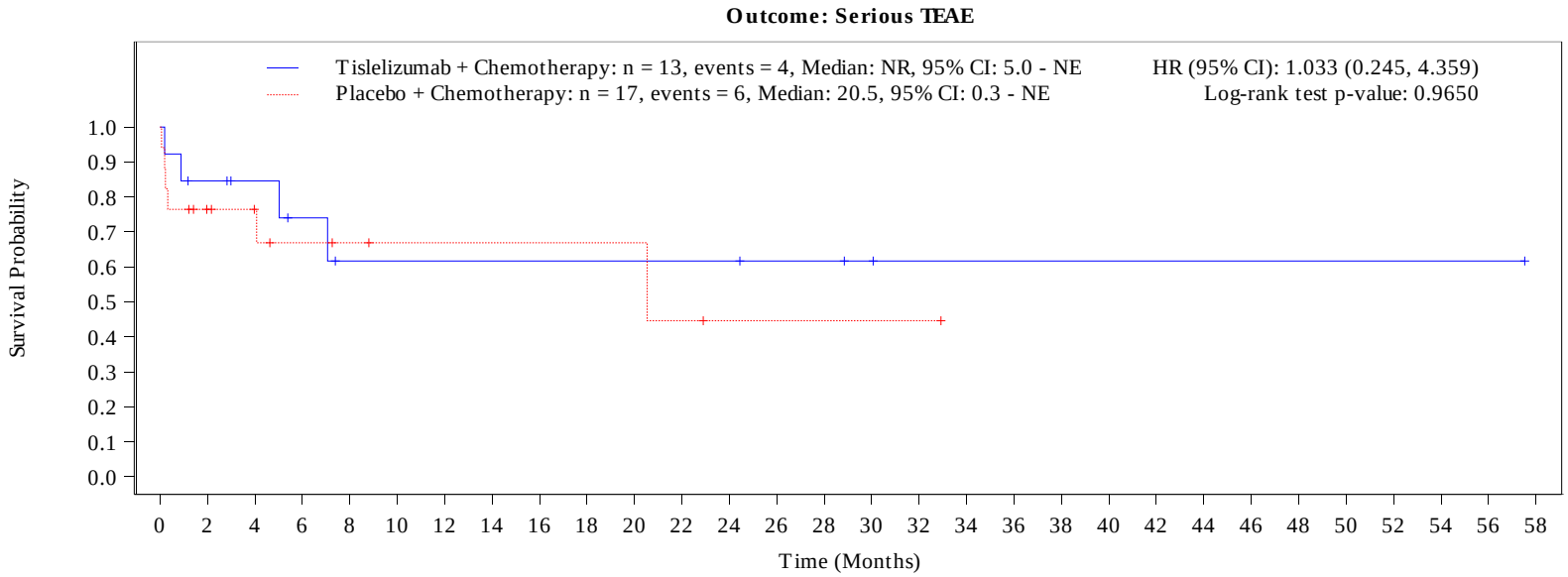
Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-tteae.sas 14NOV2024 06:03 f-14-3-1-1-km-tteae-pop1-cl.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-tteae.sas 14NOV2024 06:03 f-14-3-1-1-km-tteae-pop1-cl.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

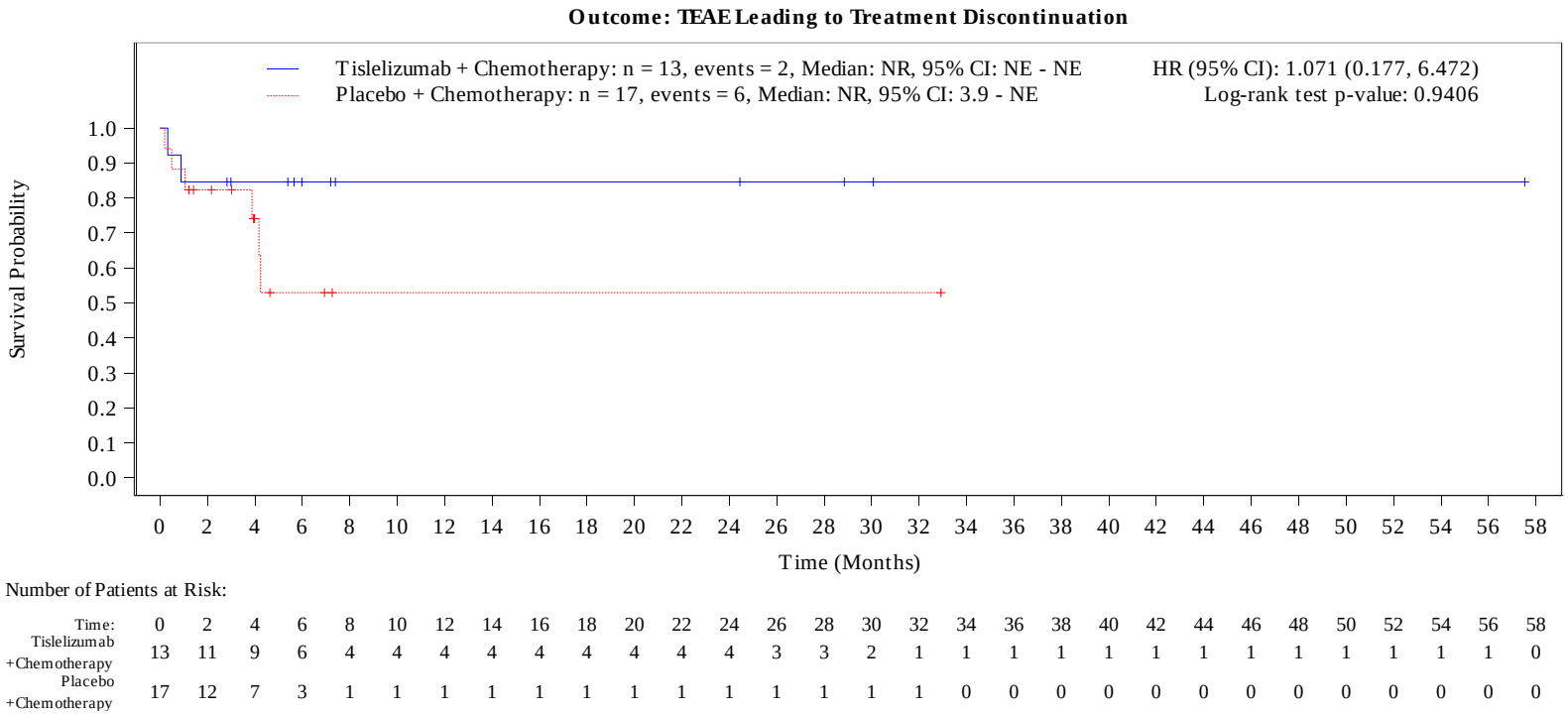


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	10	8	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	10	8	5	4	3	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-tteae.sas 14NOV2024 06:03 f-14-3-1-1-km-tteae-pop1-cl.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	7	3	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-tteae.sas 14NOV2024 06:03 f-14-3-1-1-km-tteae-pop1-cl.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	9 (100.0)	0.1 (0.0, 0.5)	8	8 (100.0)	0.1 (0.0, 0.3)	0.890 (0.323, 2.454)	0.9808
Age >= 65	4	4 (100.0)	0.1 (0.1, NE)	9	9 (100.0)	0.1 (0.0, 0.1)	1.052 (0.294, 3.762)	0.9825
Interaction								0.8740

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	9 (100.0)	0.1 (0.1, 0.1)	11	11 (100.0)	0.1 (0.0, 0.1)	0.700 (0.275, 1.782)	0.3126
Female	4	4 (100.0)	0.1 (0.0, NE)	6	6 (100.0)	0.1 (0.1, NE)	0.971 (0.244, 3.866)	0.6939
Interaction								0.7957

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	7 (100.0)	0.1 (0.1, 0.1)	10	10 (100.0)	0.1 (0.0, 0.1)	0.275 (0.076, 0.991)	0.0233
1	6	6 (100.0)	0.1 (0.0, NE)	7	7 (100.0)	0.1 (0.1, 0.3)	1.474 (0.465, 4.673)	0.4652
Interaction								0.0384

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.1 (0.1, NE)	7	7 (100.0)	0.1 (0.0, 0.1)	0.468 (0.107, 2.057)	0.2016
No	9	9 (100.0)	0.1 (0.0, 0.5)	10	10 (100.0)	0.1 (0.1, 0.3)	0.986 (0.384, 2.530)	0.9089
Interaction								0.4597

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	6 (66.7)	4.2 (0.1, NE)	8	6 (75.0)	2.1 (0.3, NE)	1.002 (0.318, 3.157)	0.9984
Age >= 65	4	4 (100.0)	0.7 (0.2, NE)	9	8 (88.9)	0.2 (0.1, 1.0)	0.586 (0.153, 2.239)	0.4168
Interaction								0.4084

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	8 (88.9)	0.7 (0.2, NE)	11	9 (81.8)	1.0 (0.2, NE)	1.072 (0.397, 2.898)	0.8967
Female	4	2 (50.0)	4.2 (0.1, NE)	6	5 (83.3)	0.9 (0.1, NE)	0.445 (0.084, 2.365)	0.3195
Interaction								0.3981
ECOG Performance Score								
0	7	6 (85.7)	0.7 (0.2, NE)	10	9 (90.0)	0.9 (0.1, 2.1)	0.887 (0.304, 2.593)	0.8329
1	6	4 (66.7)	2.6 (0.1, NE)	7	5 (71.4)	1.0 (0.1, NE)	0.831 (0.217, 3.183)	0.7833
Interaction								0.9489

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	4 (100.0)	0.5 (0.1, NE)	7	6 (85.7)	0.8 (0.1, NE)	1.481 (0.387, 5.667)	0.5460
No	9	6 (66.7)	4.2 (0.2, NE)	10	8 (80.0)	1.6 (0.2, NE)	0.654 (0.222, 1.924)	0.4392
Interaction								0.4606

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	2 (22.2)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	4 (44.4)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	0 (0.0)	--	6	3 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-tteae-subgrp.sas 14NOV2024 06:31 t-14-3-1-2-1-1-s-tteae-subgrp-pop1-cl.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	4 (40.0)	--	--	--
1	6	1 (16.7)	--	7	2 (28.6)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	3 (42.9)	--	--	--
No	9	3 (33.3)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	4 (50.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	0 (0.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE Leading to Treatment Discontinuation

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	3 (42.9)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	1 (14.3)	--	--	--
No	9	1 (11.1)	--	10	5 (50.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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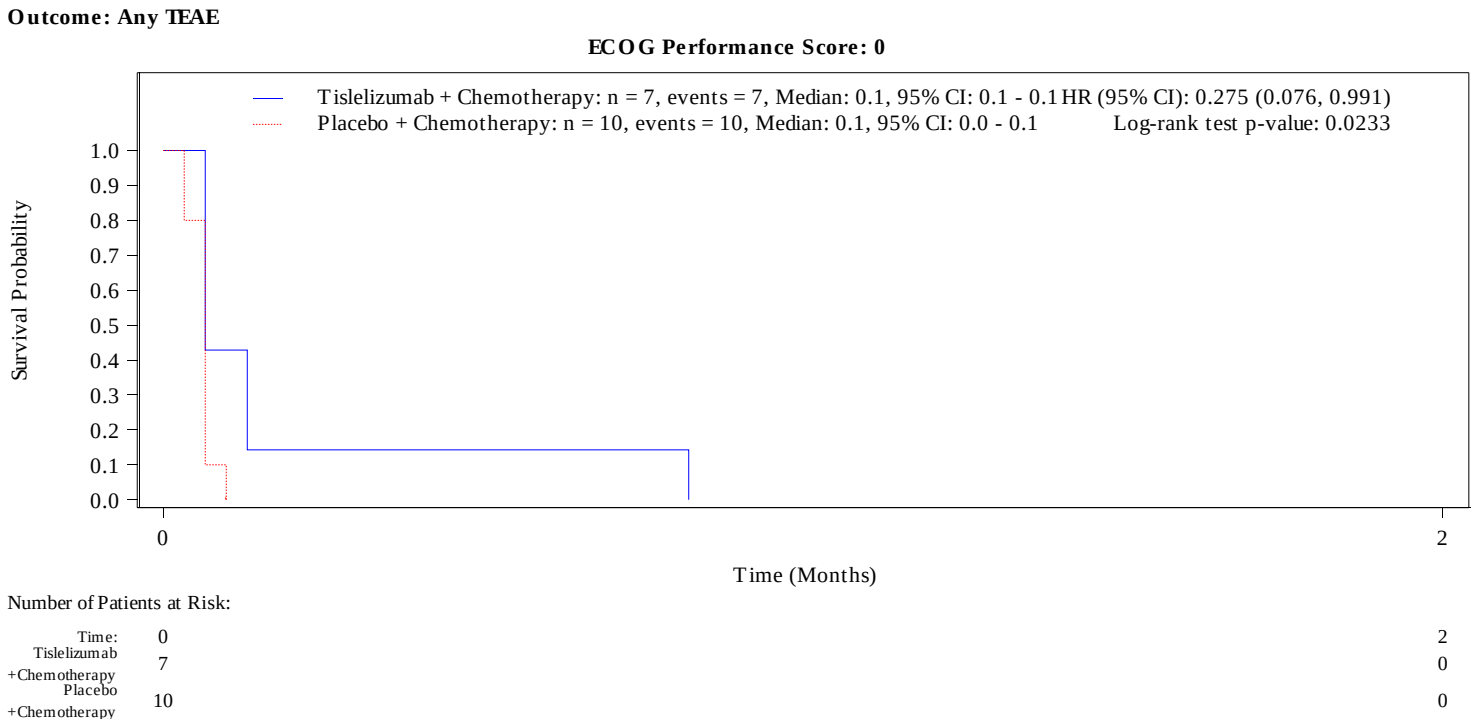
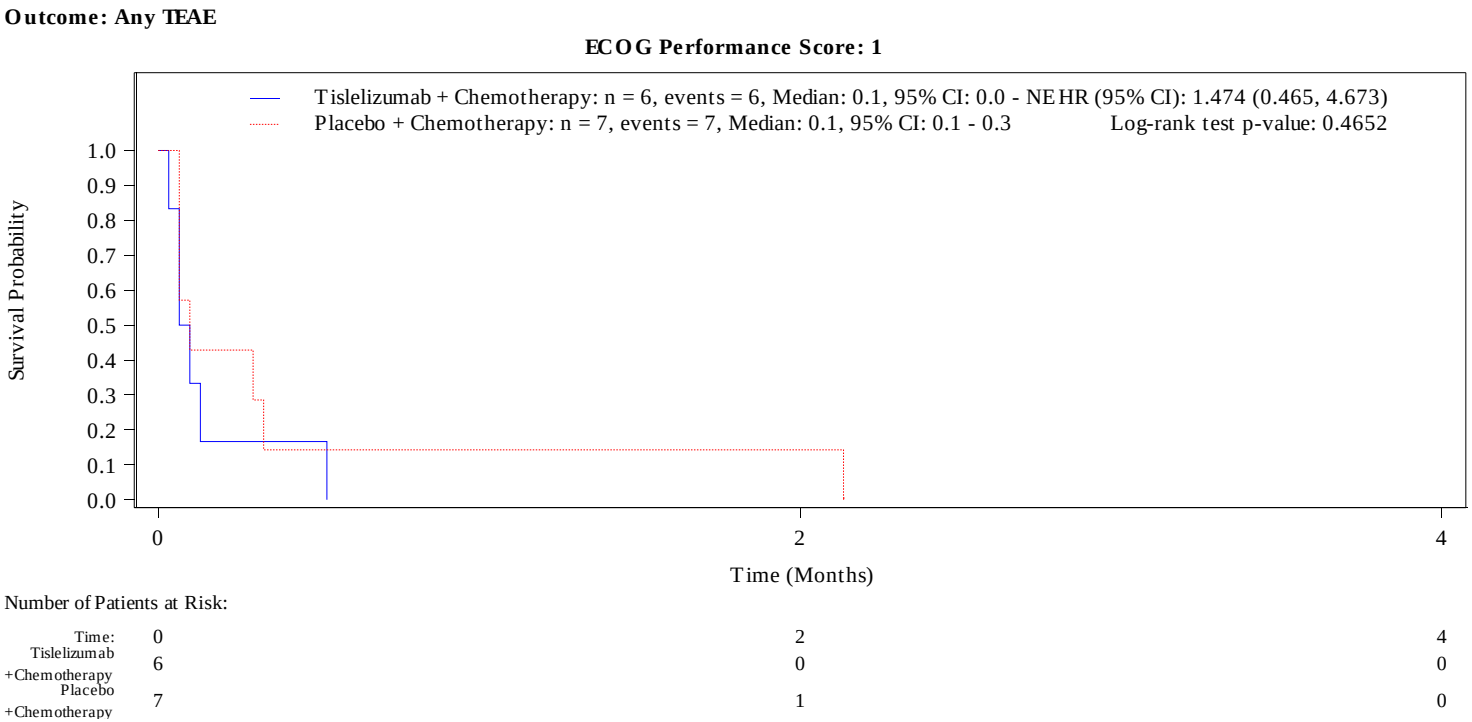
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	8 (61.5)	1.4 (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	4.057 (0.957, 17.200)	0.0451
Anaemia	13	6 (46.2)	NR (0.5, NE)	17	4 (23.5)	NR (4.0, NE)	3.407 (0.772, 15.033)	0.0923
Leukopenia	13	2 (15.4)	NR (1.3, NE)	17	1 (5.9)	NR (NE, NE)	2.442 (0.202, 29.535)	0.4712
Neutropenia	13	3 (23.1)	NR (1.4, NE)	17	3 (17.6)	NR (5.0, NE)	2.435 (0.367, 16.158)	0.3451
Endocrine disorders	13	2 (15.4)	NR (4.2, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3008

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	13	11 (84.6)	0.1 (0.1, 0.1)	17	17 (100.0)	0.1 (0.1, 0.2)	1.027 (0.408, 2.589)	0.9873
Constipation	13	9 (69.2)	0.8 (0.1, NE)	17	9 (52.9)	0.9 (0.1, NE)	0.606 (0.201, 1.833)	0.4122
Diarrhoea	13	4 (30.8)	36.1 (3.5, NE)	17	7 (41.2)	15.7 (0.8, NE)	1.092 (0.216, 5.529)	0.9152
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (20.5, NE)	NE (NE, NE)	NE
Nausea	13	5 (38.5)	NR (0.1, NE)	17	9 (52.9)	0.8 (0.1, NE)	0.775 (0.237, 2.530)	0.6705
Stomatitis	13	5 (38.5)	NR (0.2, NE)	17	7 (41.2)	NR (0.4, NE)	1.091 (0.260, 4.580)	0.9449
General disorders and administration site conditions	13	7 (53.8)	1.7 (0.1, NE)	17	12 (70.6)	0.2 (0.1, NE)	0.588 (0.216, 1.600)	0.3153

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Asthenia	13	2 (15.4)	50.4 (NE, NE)	17	4 (23.5)	NR (1.2, NE)	0.592 (0.062, 5.654)	0.6573
Fatigue	13	2 (15.4)	NR (NE, NE)	17	3 (17.6)	NR (2.3, NE)	0.493 (0.078, 3.128)	0.4453
Generalised oedema	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Malaise	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.345 (0.034, 3.496)	0.3486
Pyrexia	13	2 (15.4)	NR (3.9, NE)	17	4 (23.5)	NR (12.3, NE)	1.204 (0.161, 8.988)	0.8560
Infections and infestations	13	5 (38.5)	9.4 (1.5, NE)	17	5 (29.4)	17.5 (7.2, NE)	3.558 (0.574, 22.063)	0.1560

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia	13	2 (15.4)	NR (11.9, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urinary tract infection	13	1 (7.7)	NR (3.3, NE)	17	2 (11.8)	NR (15.1, NE)	>999.99 (0.000, NE)	0.4497
Injury, poisoning and procedural complications	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336
Fall	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1336

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	13	10 (76.9)	0.7 (0.5, 4.2)	17	8 (47.1)	5.1 (0.5, NE)	1.161 (0.387, 3.481)	0.7769
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.243 (0.022, 2.711)	0.2283

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood creatinine increased	13	2 (15.4)	NR (1.4, NE)	17	2 (11.8)	NR (4.0, NE)	0.762 (0.100, 5.803)	0.7921
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.406 (0.089, 1.851)	0.2311
Platelet count decreased	13	4 (30.8)	NR (2.9, NE)	17	1 (5.9)	32.9 (NE, NE)	>999.99 (0.000, NE)	0.0757
Weight decreased	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (5.1, NE)	0.712 (0.063, 8.022)	0.7822
White blood cell count decreased	13	4 (30.8)	NR (4.2, NE)	17	6 (35.3)	NR (1.6, NE)	0.204 (0.039, 1.080)	0.0415

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	13	10 (76.9)	1.8 (0.5, NE)	17	9 (52.9)	6.5 (0.5, NE)	1.352 (0.454, 4.025)	0.5963
Decreased appetite	13	7 (53.8)	6.7 (0.8, NE)	17	4 (23.5)	NR (6.7, NE)	2.575 (0.588, 11.282)	0.1983
Hyperglycaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1614
Hyperuricaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1086
Hypokalaemia	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (NE, NE)	0.555 (0.056, 5.515)	0.6104
Hyponatraemia	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.614 (0.052, 7.308)	0.6974
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (6.5, NE)	0.000 (0.000, NE)	0.1614

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	14.6 (9.3, NE)	2.236 (0.111, 44.877)	0.5930
Nervous system disorders	13	3 (23.1)	46.0 (5.4, NE)	17	9 (52.9)	3.3 (0.3, NE)	0.211 (0.041, 1.086)	0.0461
Dysgeusia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2945
Headache	13	2 (15.4)	49.0 (NE, NE)	17	1 (5.9)	NR (NE, NE)	1.118 (0.062, 20.117)	0.9397
Peripheral sensory neuropathy	13	2 (15.4)	NR (5.4, NE)	17	3 (17.6)	NR (3.3, NE)	0.700 (0.100, 4.925)	0.7195

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Psychiatric disorders	13	2 (15.4)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072
Insomnia	13	1 (7.7)	NR (6.8, NE)	17	5 (29.4)	19.0 (2.4, NE)	0.185 (0.019, 1.761)	0.1072
Renal and urinary disorders	13	1 (7.7)	NR (4.7, NE)	17	5 (29.4)	NR (2.8, NE)	0.176 (0.019, 1.637)	0.0892
Chronic kidney disease	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Renal impairment	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.2, NE)	0.000 (0.000, NE)	0.0564
Respiratory, thoracic and mediastinal disorders	13	6 (46.2)	6.2 (1.1, NE)	17	9 (52.9)	2.4 (0.2, NE)	0.793 (0.248, 2.534)	0.7245

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Cough	13	2 (15.4)	NR (16.5, NE)	17	1 (5.9)	NR (NE, NE)	1.768 (0.075, 41.454)	0.7221
Hiccups	13	2 (15.4)	NR (NE, NE)	17	4 (23.5)	NR (2.4, NE)	0.283 (0.049, 1.624)	0.1387
Pneumonia aspiration	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	21.4 (21.4, NE)	1.000 (0.053, 18.915)	1.0000

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	13	6 (46.2)	6.9 (1.2, NE)	17	7 (41.2)	12.9 (1.2, NE)	0.932 (0.251, 3.464)	0.8956
Alopecia	13	2 (15.4)	NR (3.3, NE)	17	1 (5.9)	NR (NE, NE)	2.631 (0.211, 32.795)	0.4396
Palmar-plantar erythrodysaesthesia syndrome	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.6, NE)	0.000 (0.000, NE)	0.3173
Pruritus	13	3 (23.1)	NR (4.7, NE)	17	1 (5.9)	NR (12.9, NE)	>999.99 (0.000, NE)	0.4190
Rash	13	2 (15.4)	NR (6.9, NE)	17	1 (5.9)	NR (NE, NE)	1.699 (0.135, 21.378)	0.6790

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Vascular disorders	13	2 (15.4)	NR (5.4, NE)	17	4 (23.5)	NR (3.5, NE)	0.181 (0.019, 1.744)	0.1049
Flushing	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0673

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	13	2 (15.4)	NR (1.6, NE)	17	4 (23.5)	NR (4.0, NE)	0.819 (0.123, 5.460)	0.8364
Anaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.0, NE)	0.000 (0.000, NE)	0.0859
Leukopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Lymphopenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Neutropenia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (5.0, NE)	0.000 (0.000, NE)	0.2008
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Eye disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859
Cataract	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.1859

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	5 (29.4)	NR (1.1, NE)	0.424 (0.042, 4.291)	0.4580
Acquired soft palate fissure	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Diarrhoea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.630 (0.049, 8.140)	0.7214

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	13	2 (15.4)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0325
Asthenia	13	2 (15.4)	55.9 (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Fatigue	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.3173

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	13	2 (15.4)	NR (5.0, NE)	17	1 (5.9)	NR (NE, NE)	7.027 (0.614, 80.430)	0.0717
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Investigations	13	4 (30.8)	NR (0.9, NE)	17	5 (29.4)	NR (2.1, NE)	0.376 (0.084, 1.686)	0.1984
Amylase increased	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4795
Lipase increased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0617

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Neutrophil count decreased	13	4 (30.8)	NR (0.9, NE)	17	4 (23.5)	NR (2.1, NE)	0.844 (0.197, 3.605)	0.8183
White blood cell count decreased	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.4, NE)	0.000 (0.000, NE)	0.1499
Metabolism and nutrition disorders	13	3 (23.1)	NR (1.8, NE)	17	5 (29.4)	11.2 (4.1, NE)	0.737 (0.126, 4.302)	0.7342
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	3.162 (0.184, 54.388)	0.4054
Hyperkalaemia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Hypoglycaemia	13	1 (7.7)	NR (17.2, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	3 (17.6)	NR (4.1, NE)	0.000 (0.000, NE)	0.1439
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Hypophosphataemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (11.2, NE)	0.000 (0.000, NE)	0.4795
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-tteae-socpt.sas 14NOV2024 02:06 t-14-3-1-2-2-3-1-tteae-socpt-gr3-pop1-cl.rtf

Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Skin and subcutaneous tissue disorders	13	2 (15.4)	41.2 (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Rash	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Skin toxicity	13	1 (7.7)	41.2 (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Endocrine disorders	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Hypopituitarism	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5271
Gastrointestinal disorders	13	1 (7.7)	NR (NE, NE)	17	3 (17.6)	NR (20.5, NE)	0.821 (0.062, 10.940)	0.8814
Dysphagia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (20.5, NE)	NE (NE, NE)	NE
Nausea	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Oesophageal stenosis	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.6547

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Stomatitis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
General disorders and administration site conditions	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Asthenia	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	13	3 (23.1)	NR (1.5, NE)	17	1 (5.9)	NR (NE, NE)	7.889 (0.745, 83.509)	0.0530
Pneumonia	13	1 (7.7)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	4.472 (0.279, 71.808)	0.2467
Pulmonary tuberculosis	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.4292
Urethritis	13	1 (7.7)	NR (5.0, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	13	1 (7.7)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	1.000 (0.081, 12.270)	1.0000
Decreased appetite	13	1 (7.7)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.0253
Hypokalaemia	13	0 (0.0)	NR (NE, NE)	17	2 (11.8)	NR (4.1, NE)	0.000 (0.000, NE)	0.2253
Hyponatraemia	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Nervous system disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059
Presyncope	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.2059

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Placebo + Chemotherapy (N = 17) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Renal and urinary disorders	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Acute kidney injury	13	1 (7.7)	NR (5.7, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Respiratory, thoracic and mediastinal disorders	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795
Pneumonia aspiration	13	0 (0.0)	NR (NE, NE)	17	1 (5.9)	NR (NE, NE)	0.000 (0.000, NE)	0.4795

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Patients with at Least One TEAE Leading to Any Treatment Discontinuation	2 (15.4)	6 (35.3)
General disorders and administration site conditions	1 (7.7)	0 (0.0)
Asthenia	1 (7.7)	0 (0.0)
Metabolism and nutrition disorders	1 (7.7)	0 (0.0)
Decreased appetite	1 (7.7)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (7.7)	0 (0.0)
Rash	1 (7.7)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	1 (5.9)
Acquired soft palate fissure	0 (0.0)	1 (5.9)

Source: ADSL, ADAE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.
Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
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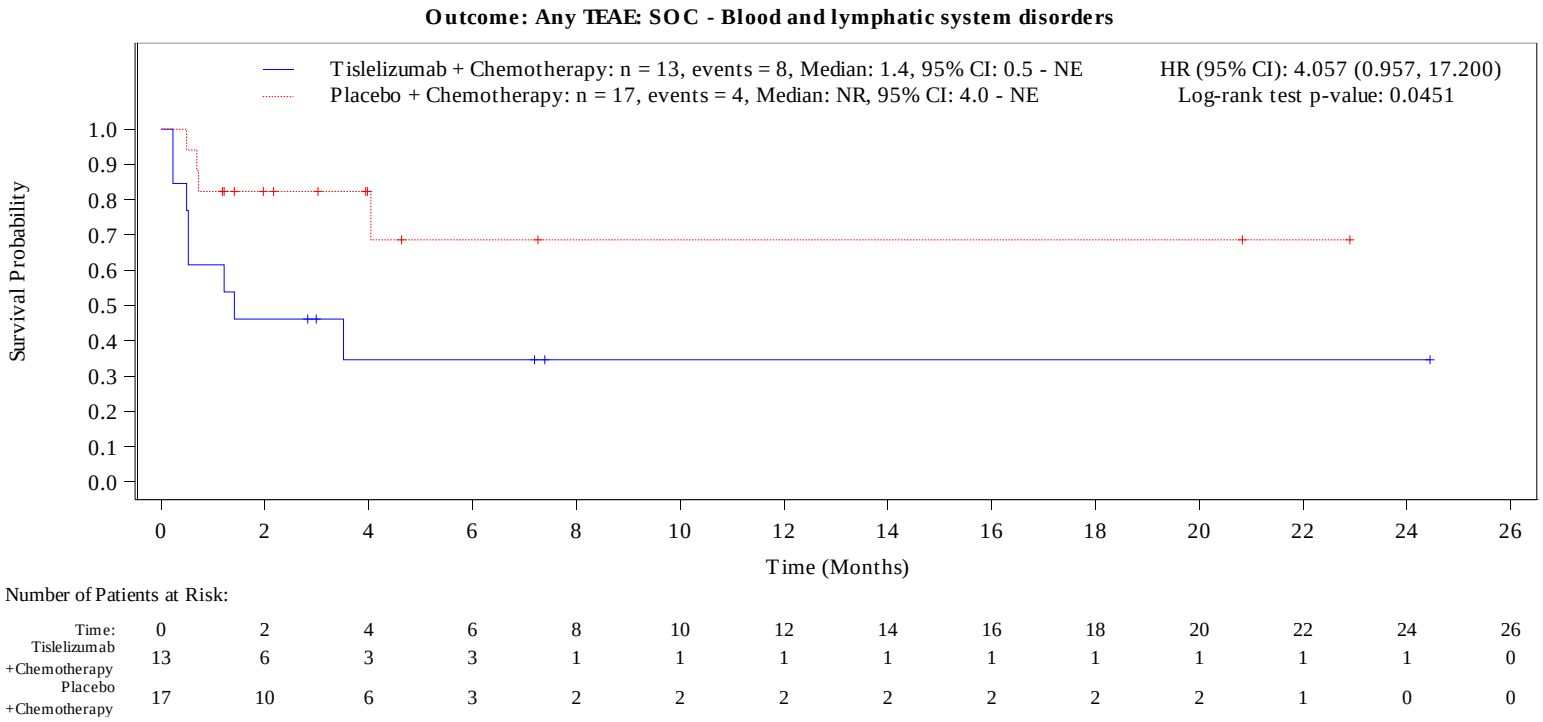
Table 14.3.1.5.1:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

System Organ Class Preferred Term	Tislelizumab + Chemotherapy (N = 13) n (%)	Placebo + Chemotherapy (N = 17) n (%)
Infections and infestations	0 (0.0)	1 (5.9)
Pneumonia	0 (0.0)	1 (5.9)
Nervous system disorders	0 (0.0)	1 (5.9)
Peripheral sensory neuropathy	0 (0.0)	1 (5.9)
Renal and urinary disorders	0 (0.0)	3 (17.6)
Chronic kidney disease	0 (0.0)	1 (5.9)
Renal impairment	0 (0.0)	2 (11.8)

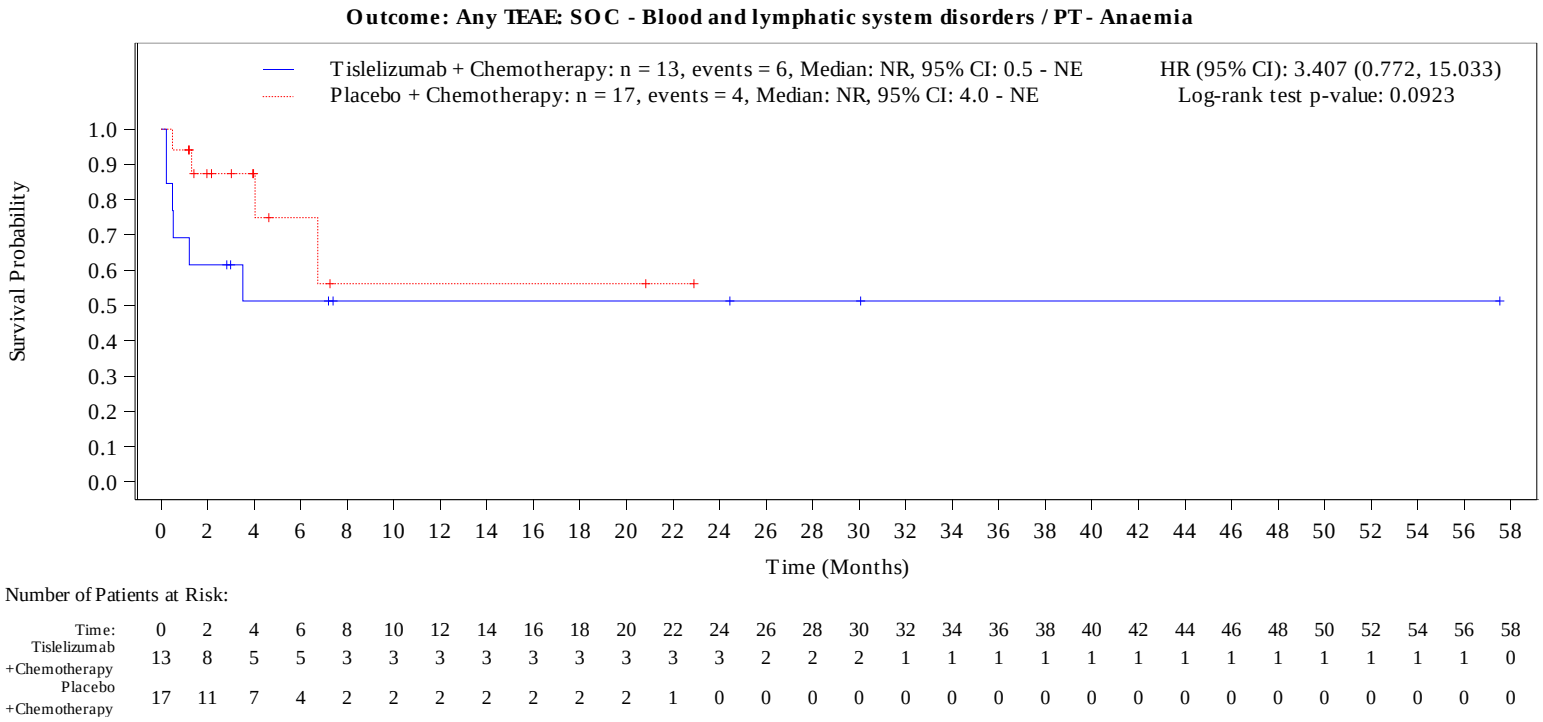
Source: ADSL, ADAE. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0.
Adverse Events are sorted by decreasing frequency of system organ class then descending frequency of preferred term within system organ class in Tislelizumab + Chemotherapy column.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-socpt.sas 14NOV2024 02:07 t-14-3-1-5-1-socpt-dis-pop1-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-aesocpt.sas 14NOV2024 06:03 f-14-3-1-2-km-aesocpt-teae-pop1-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	8	5	5	3	3	3	3	3	3	3	3	3	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	7	4	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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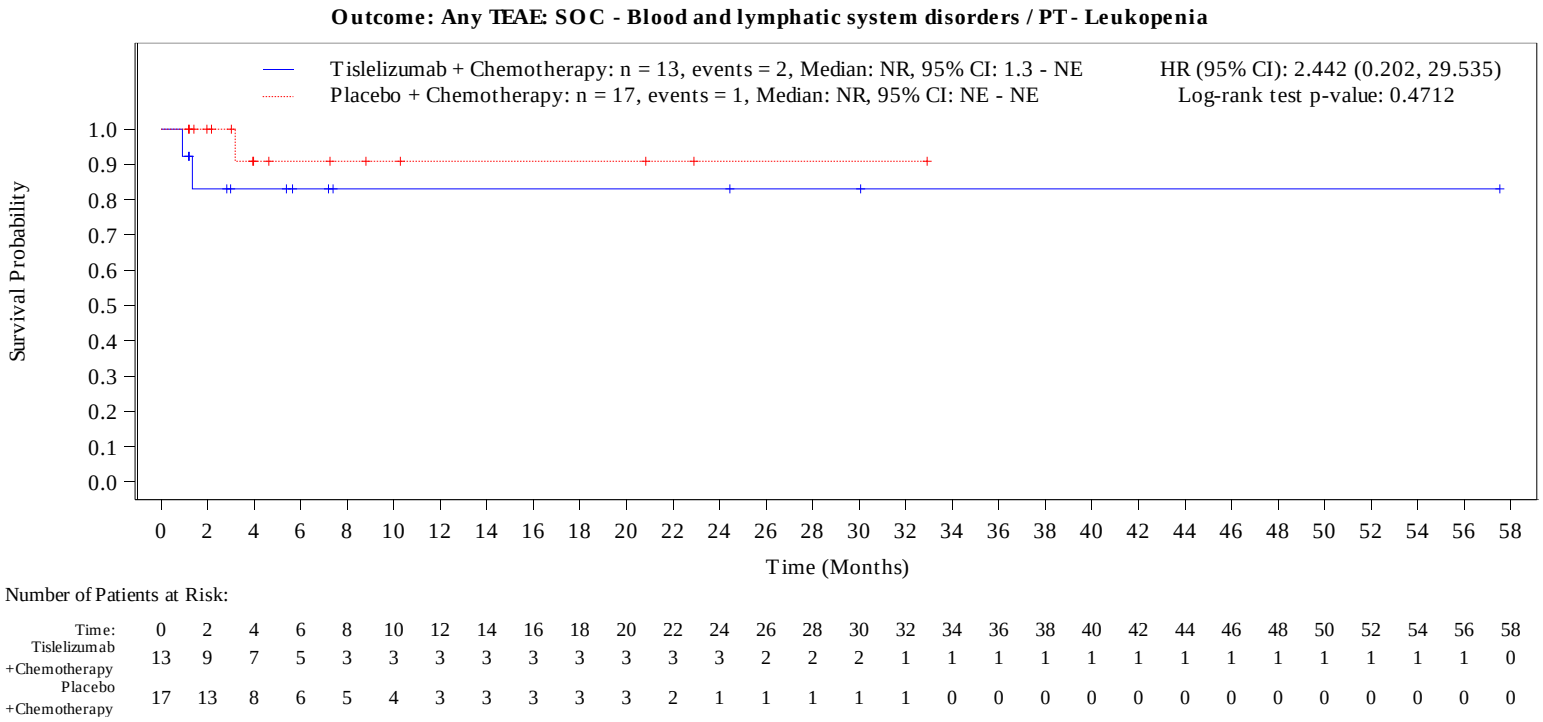
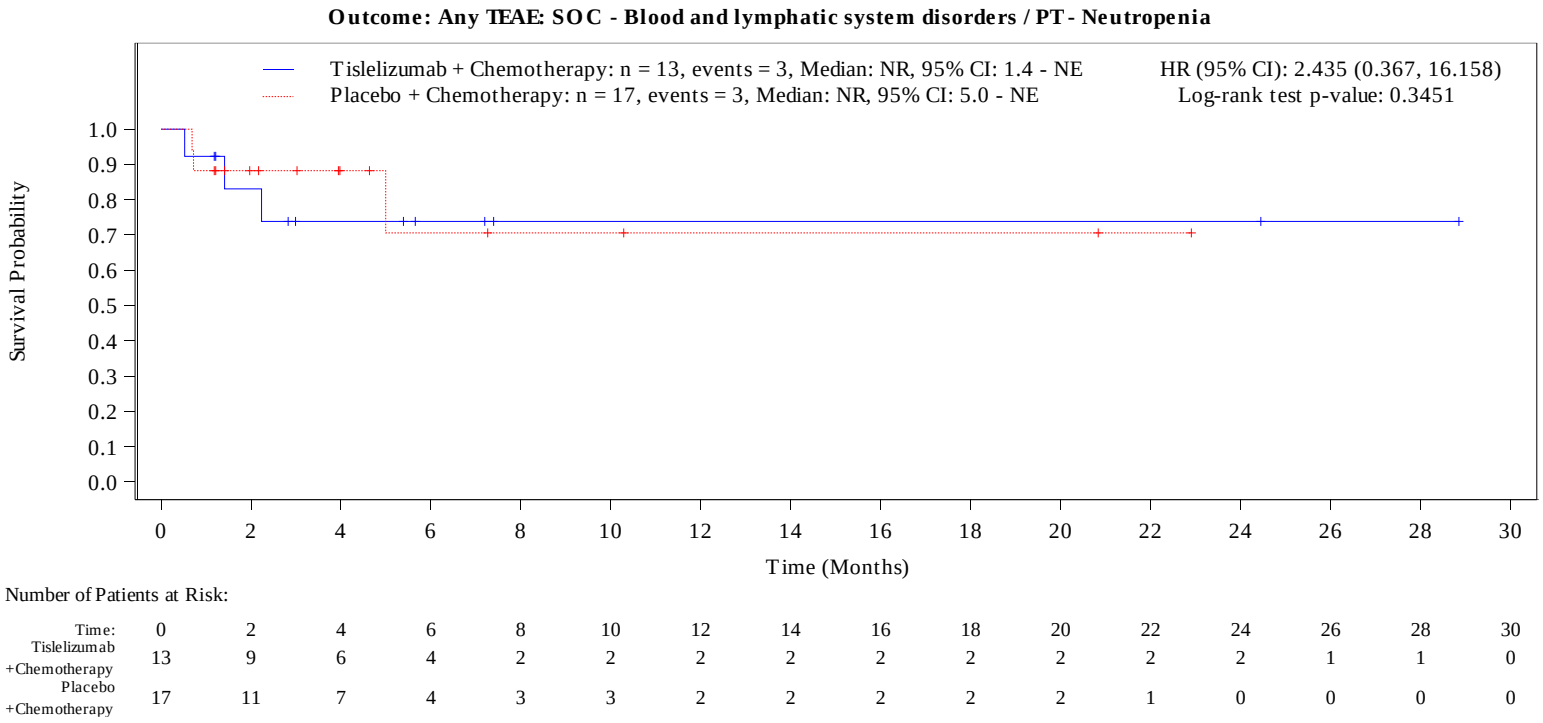
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-aesocpt.sas 14NOV2024 06:03 f-14-3-1-2-km-aesocpt-teae-pop1-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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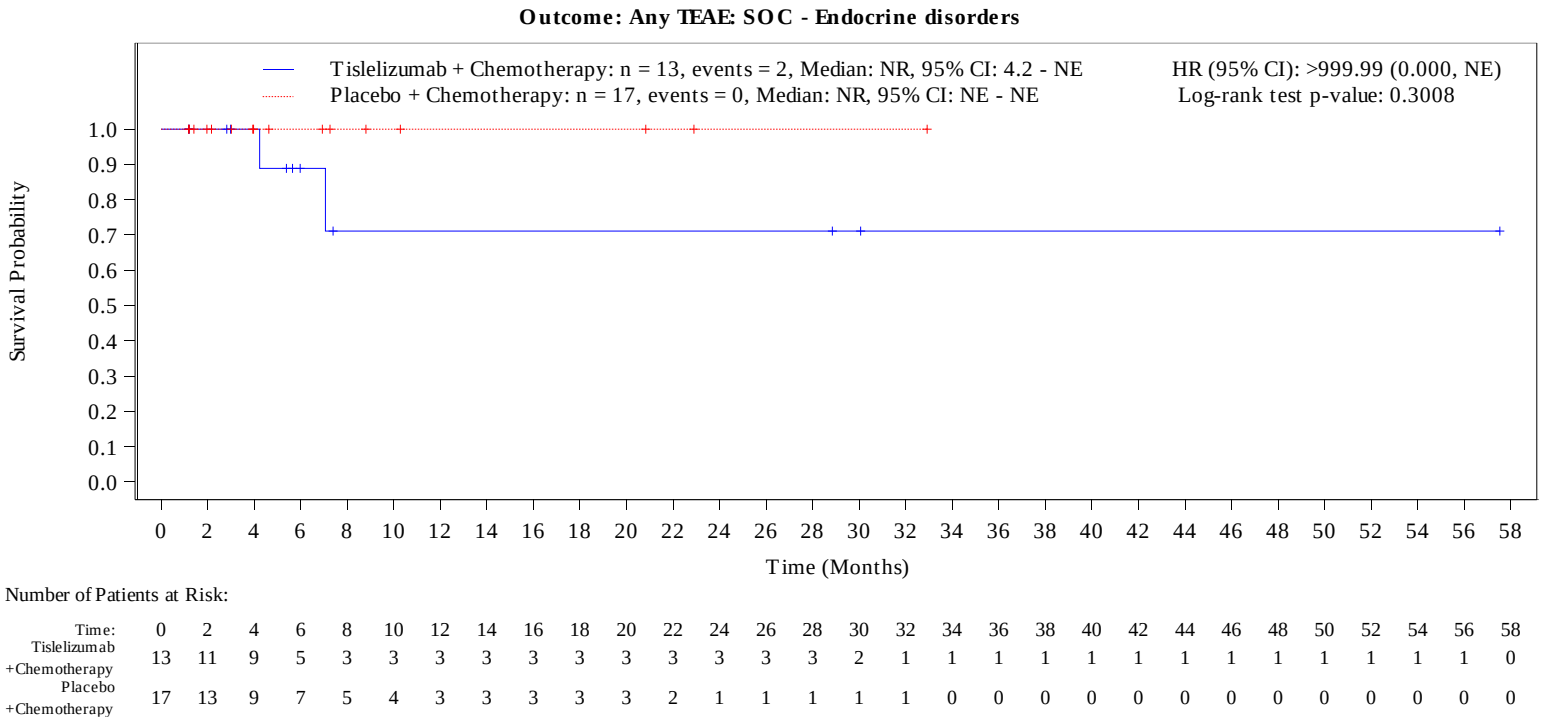

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	5	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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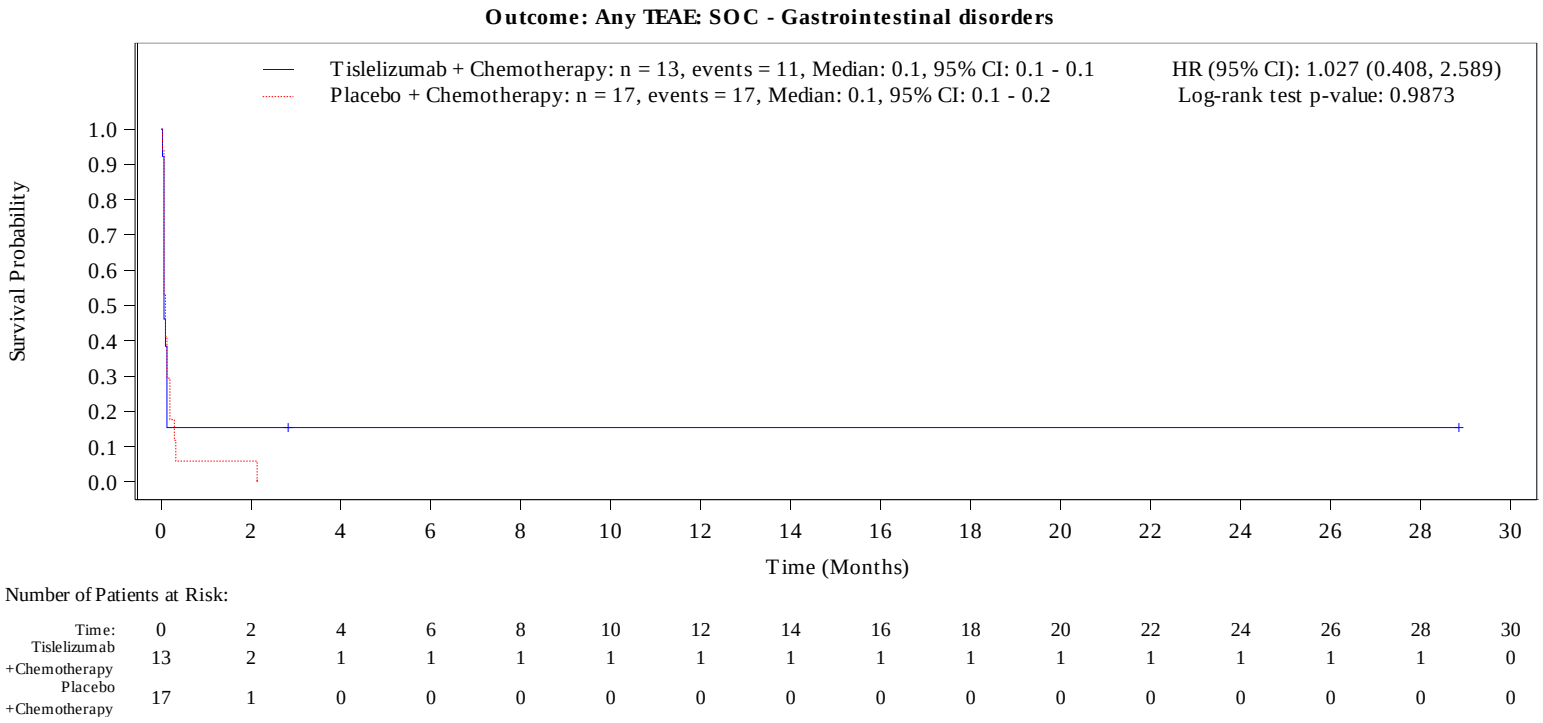
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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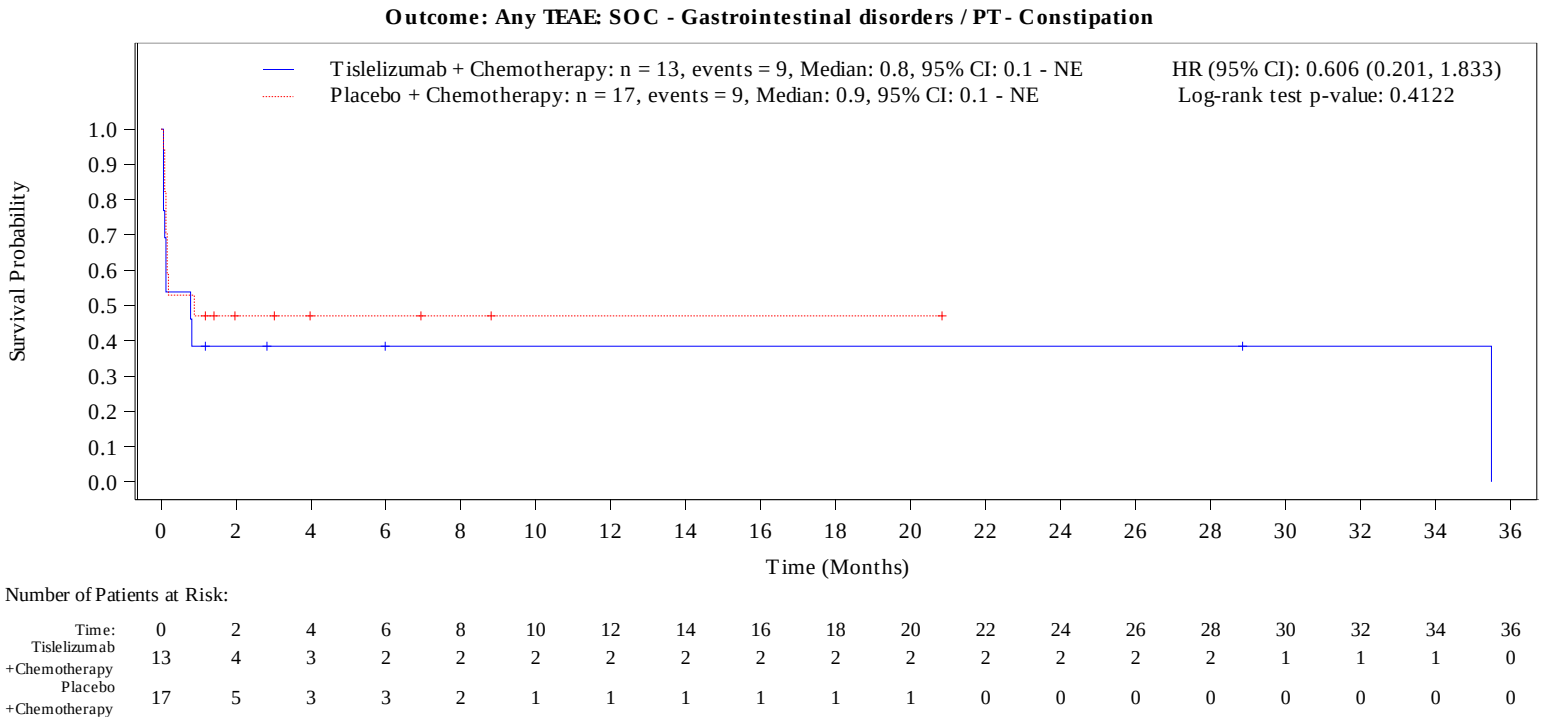

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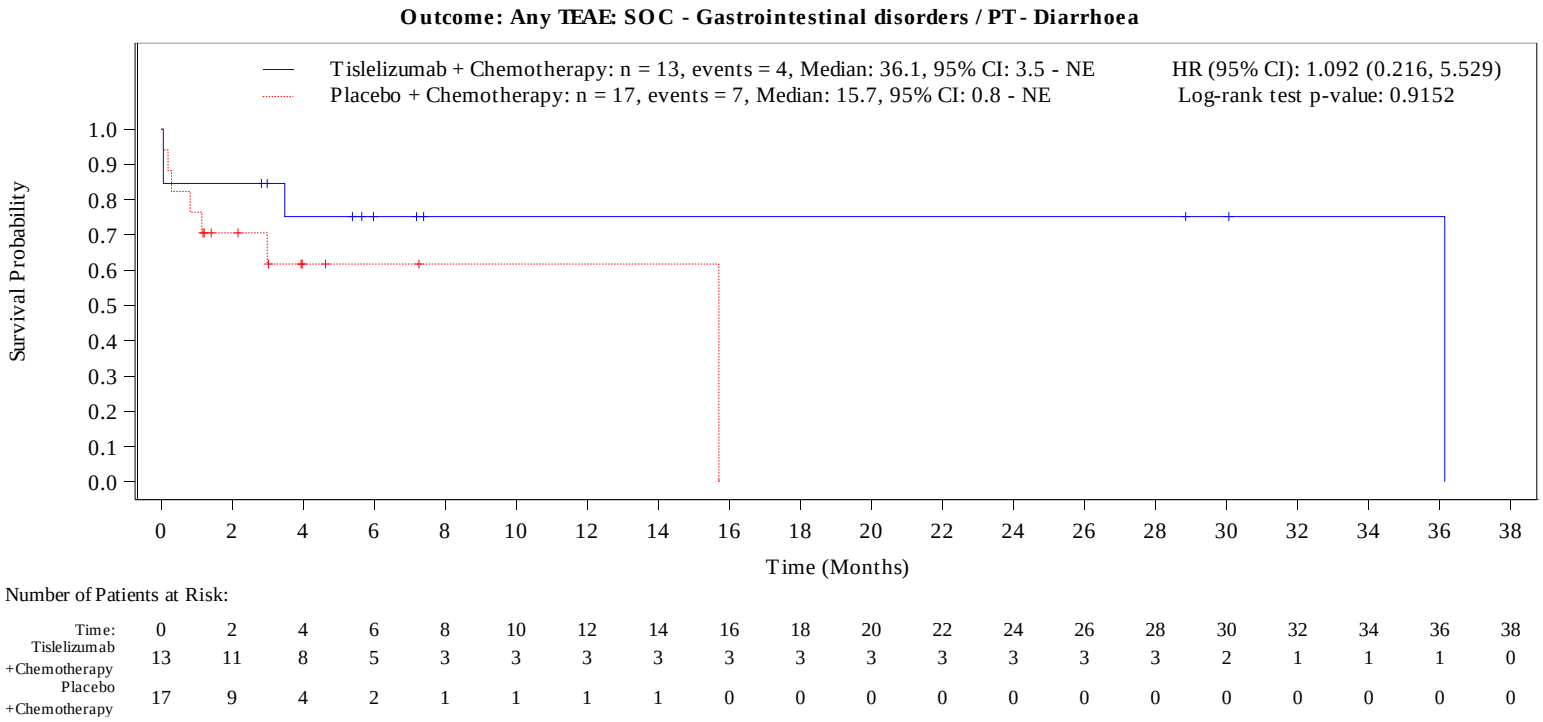

Number of Patients at Risk:

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Placebo +Chemotherapy	17	9	4	2	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

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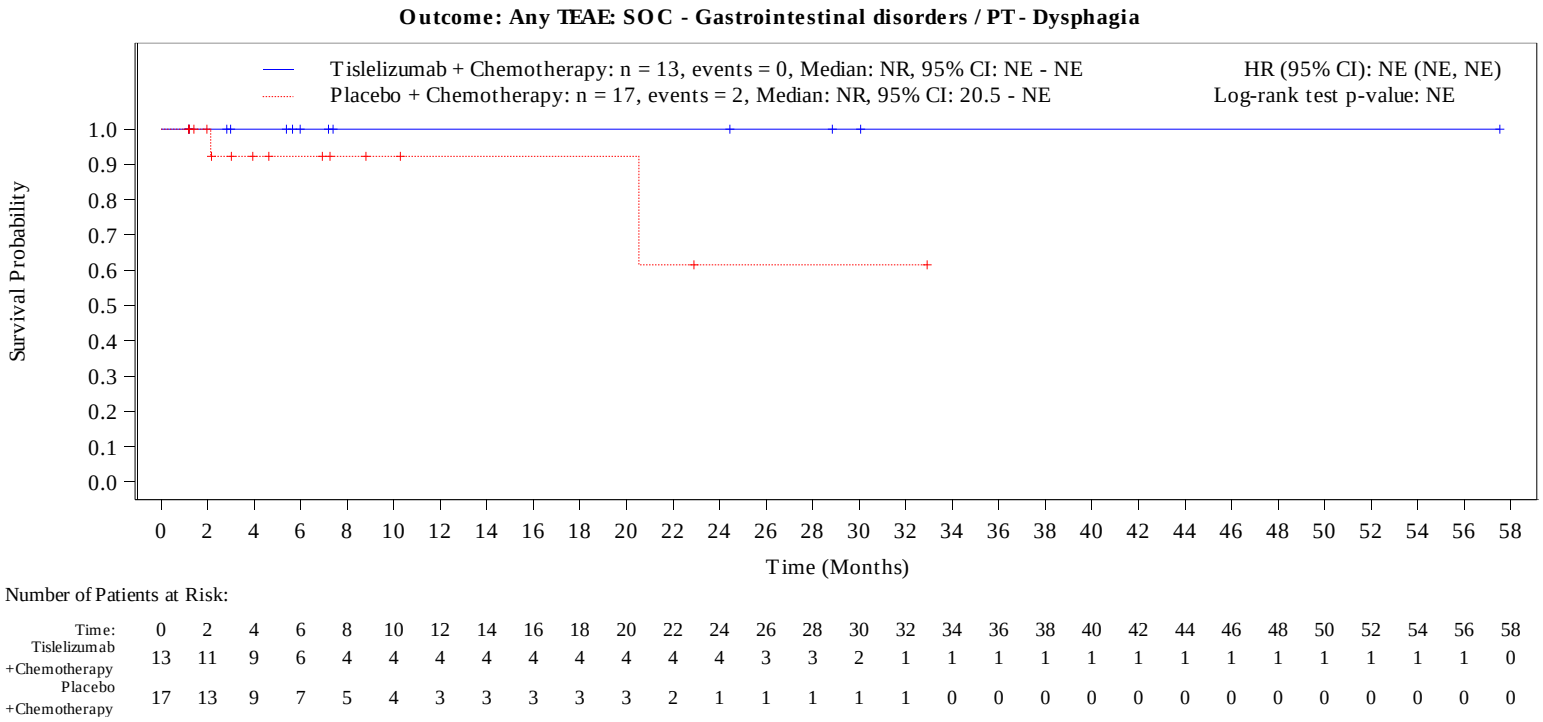

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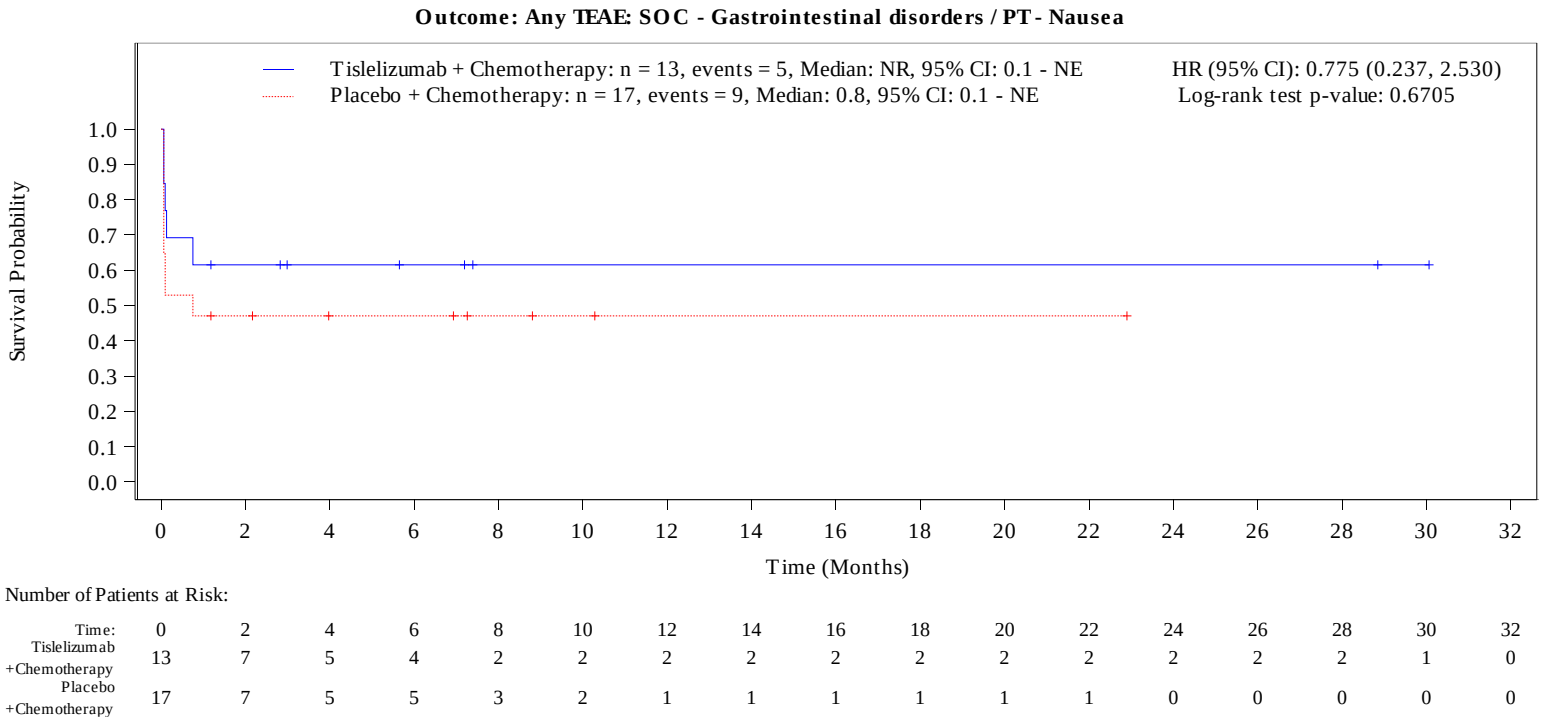

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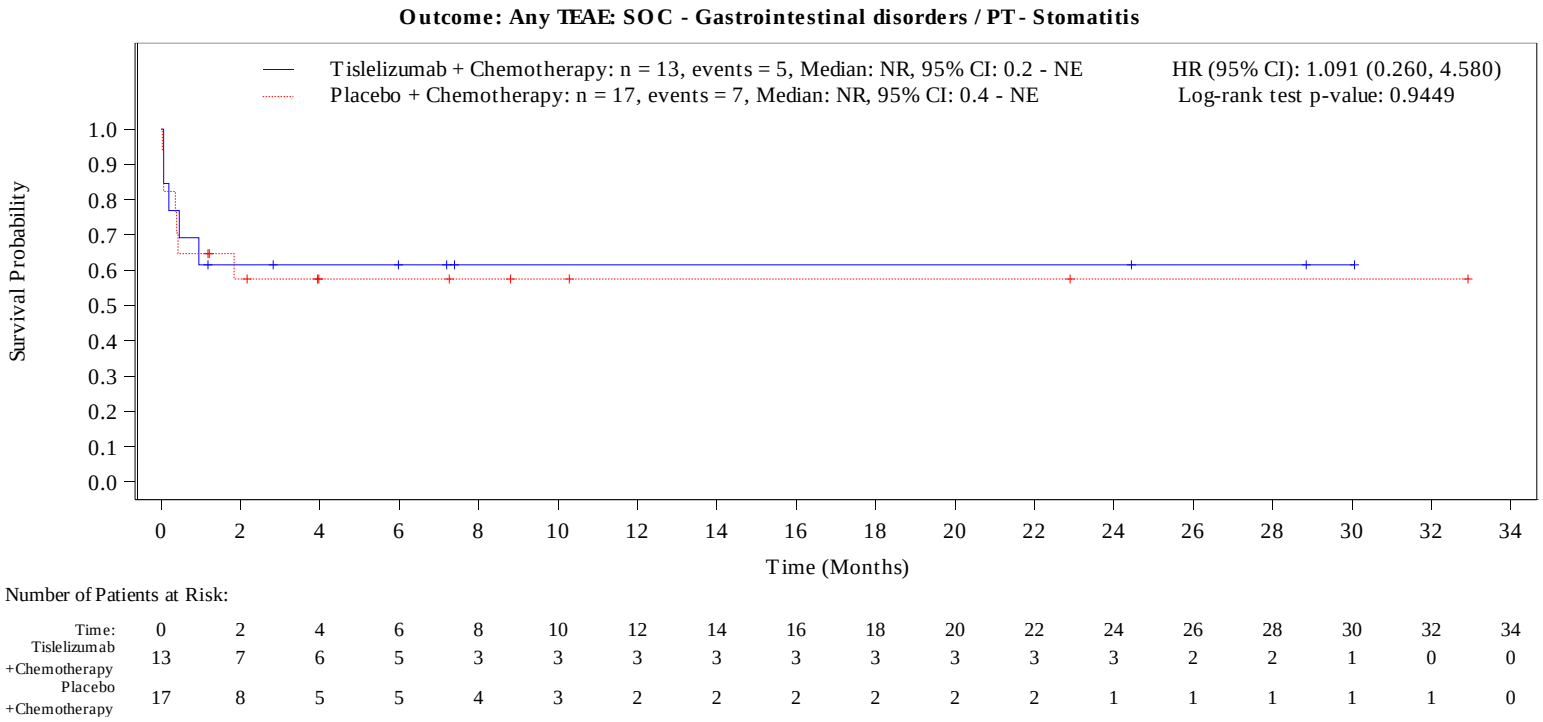

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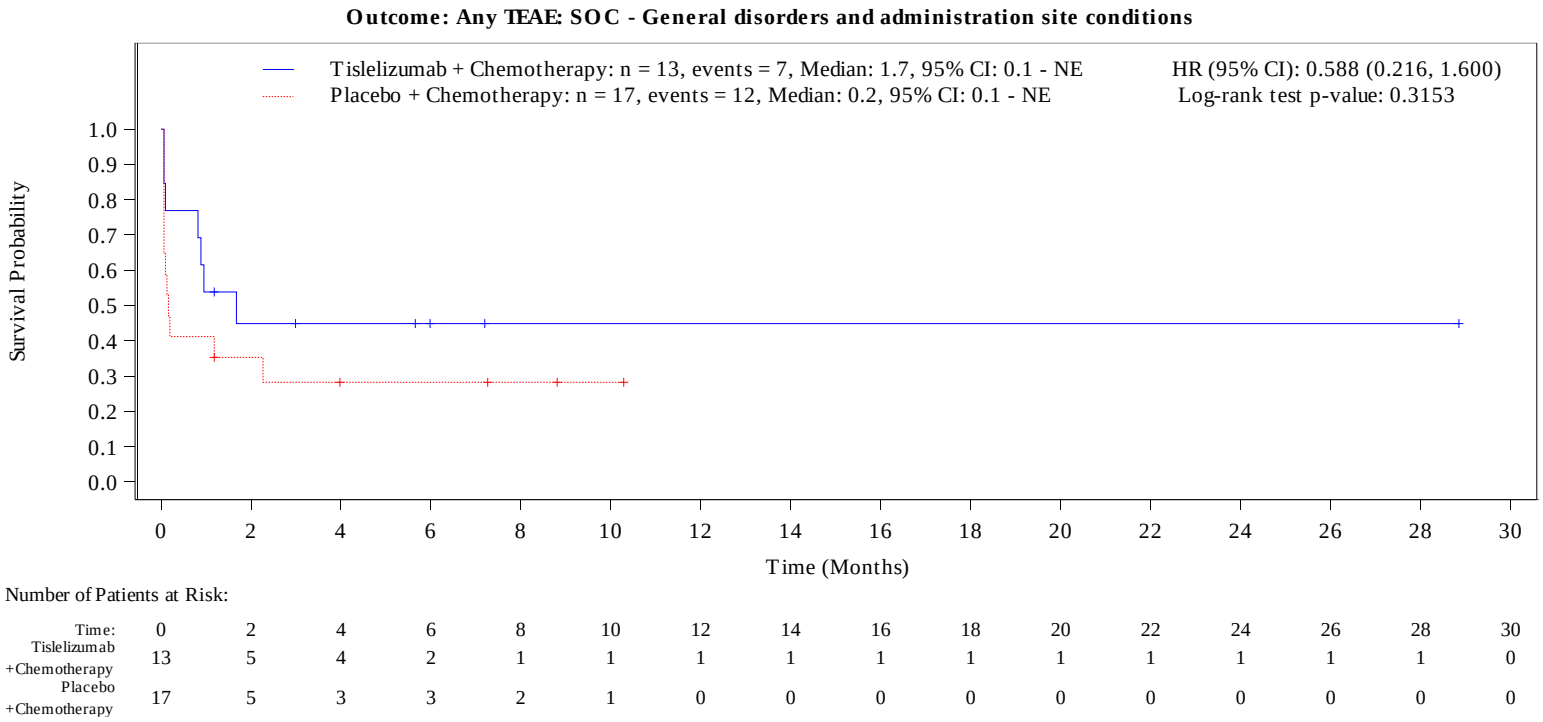

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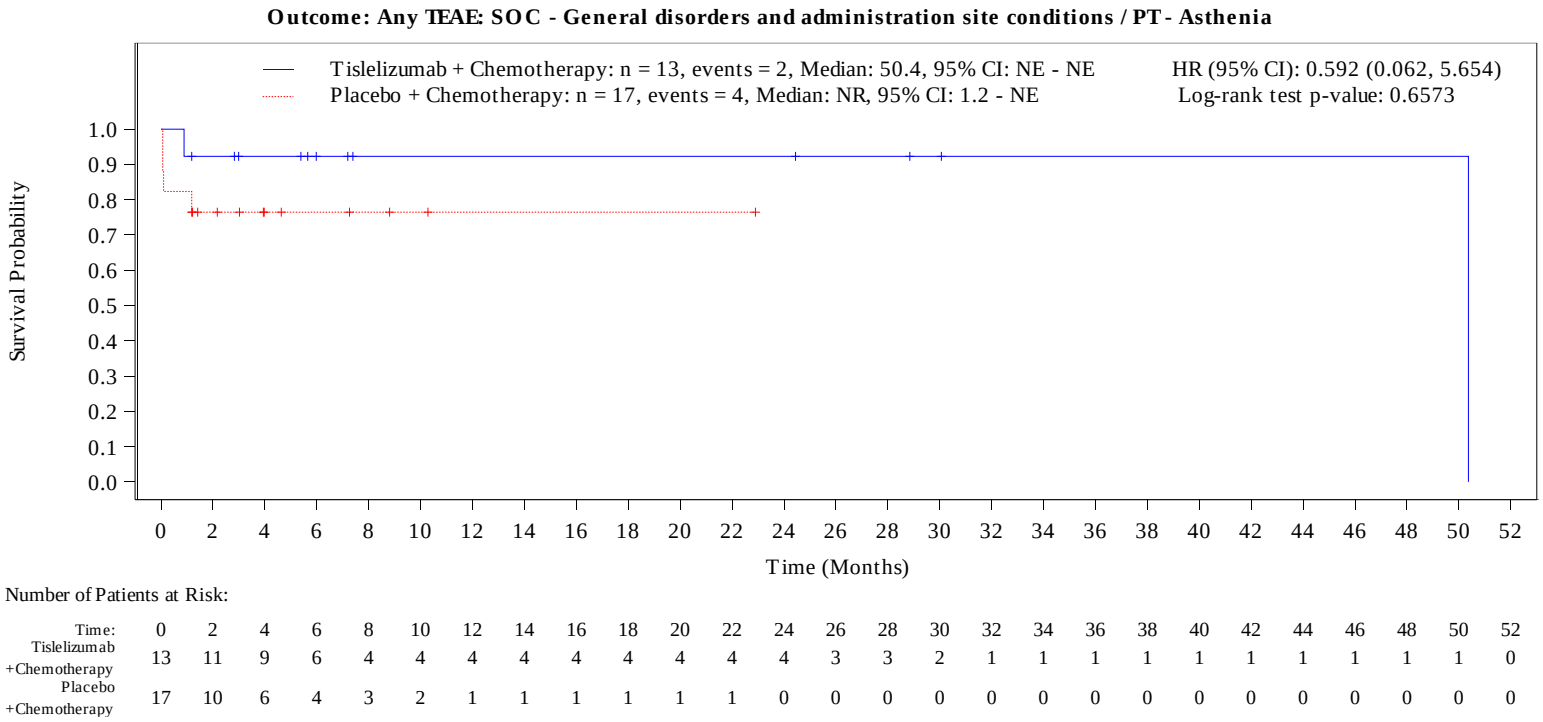

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	10	6	4	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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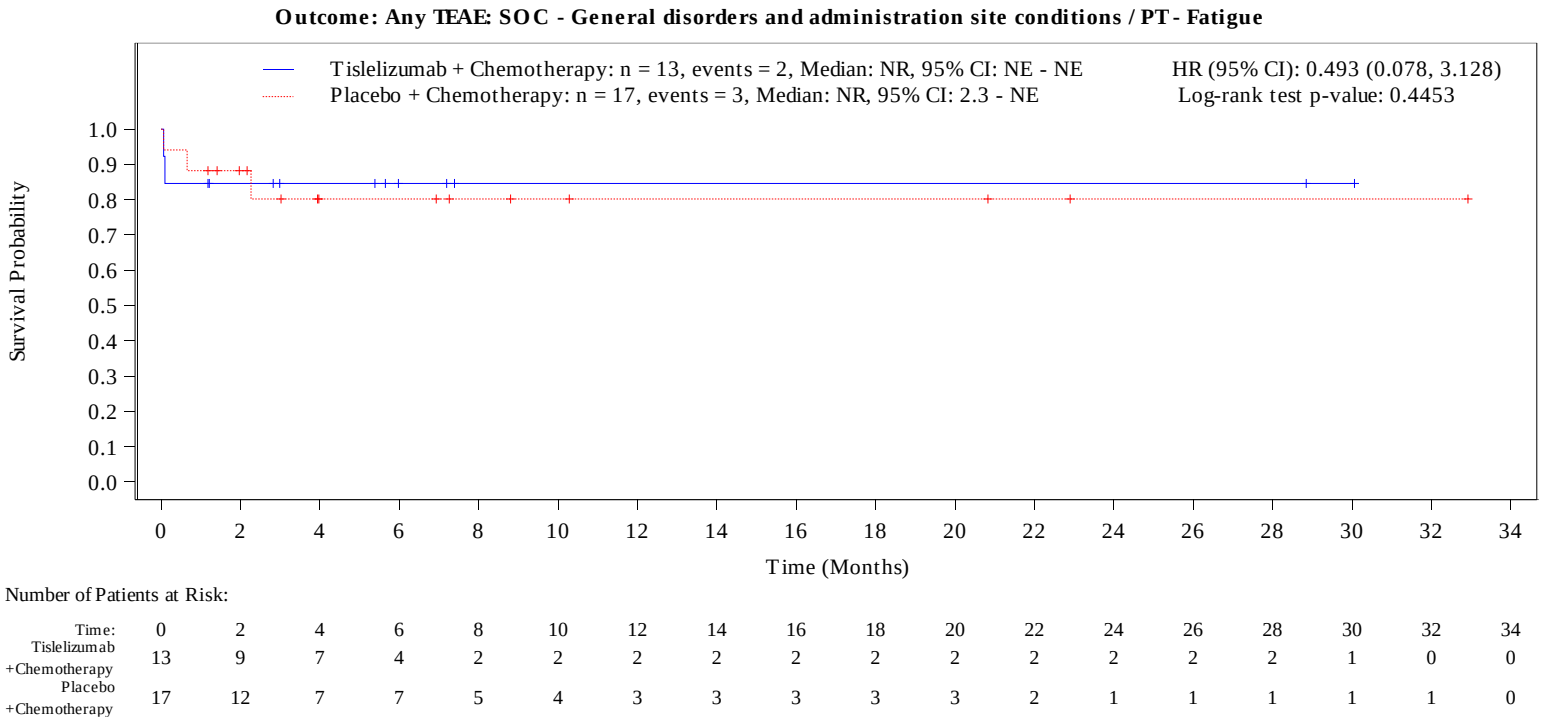
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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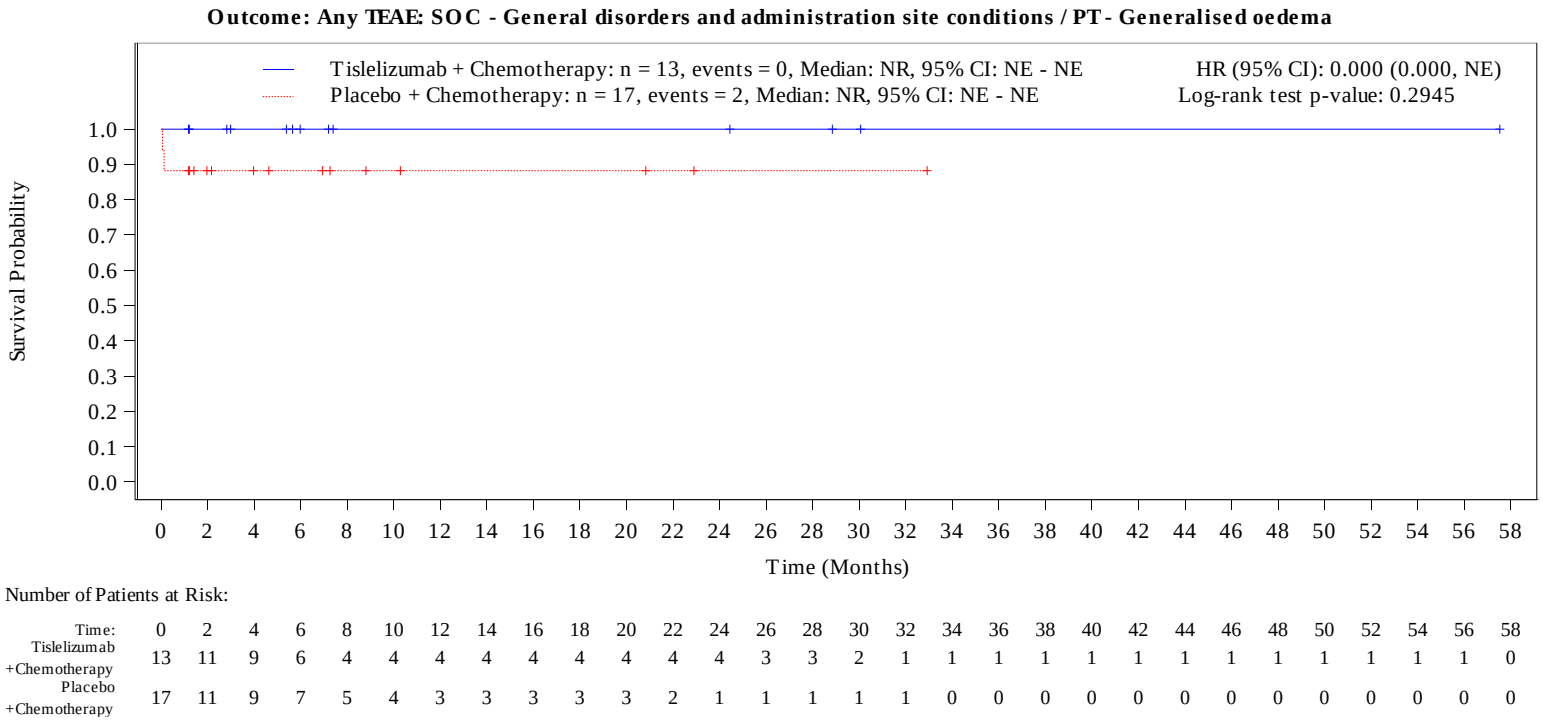

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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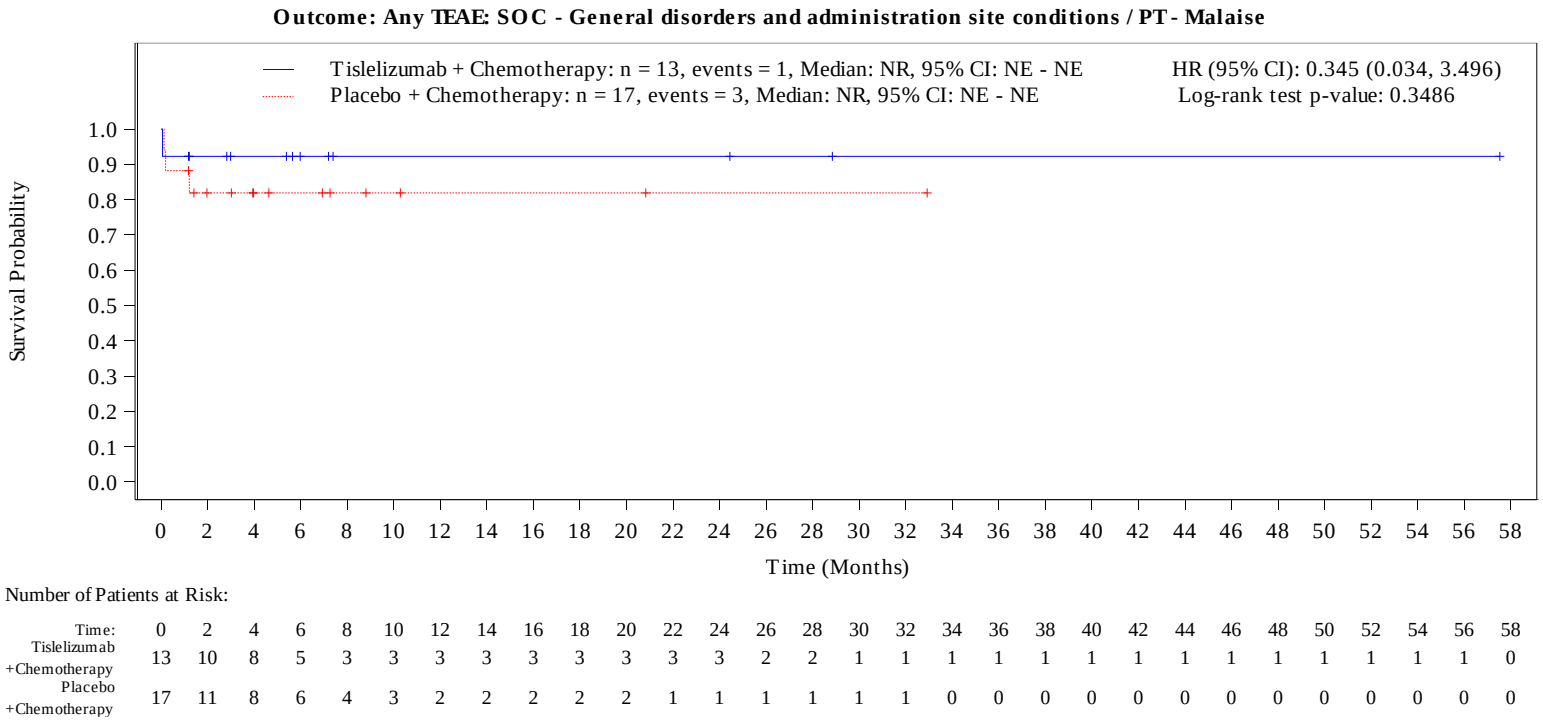
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	10	8	5	3	3	3	3	3	3	3	3	3	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	8	6	4	3	2	2	2	2	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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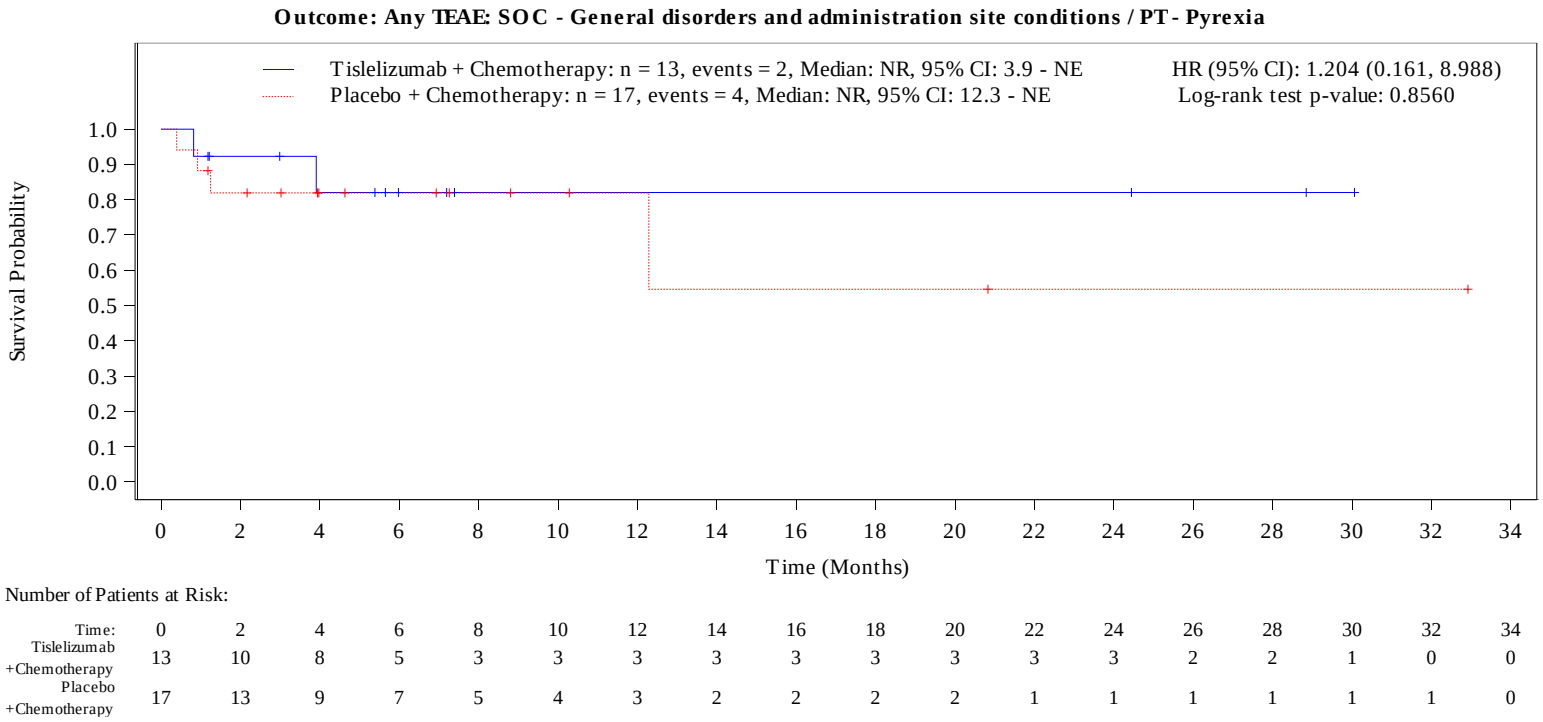

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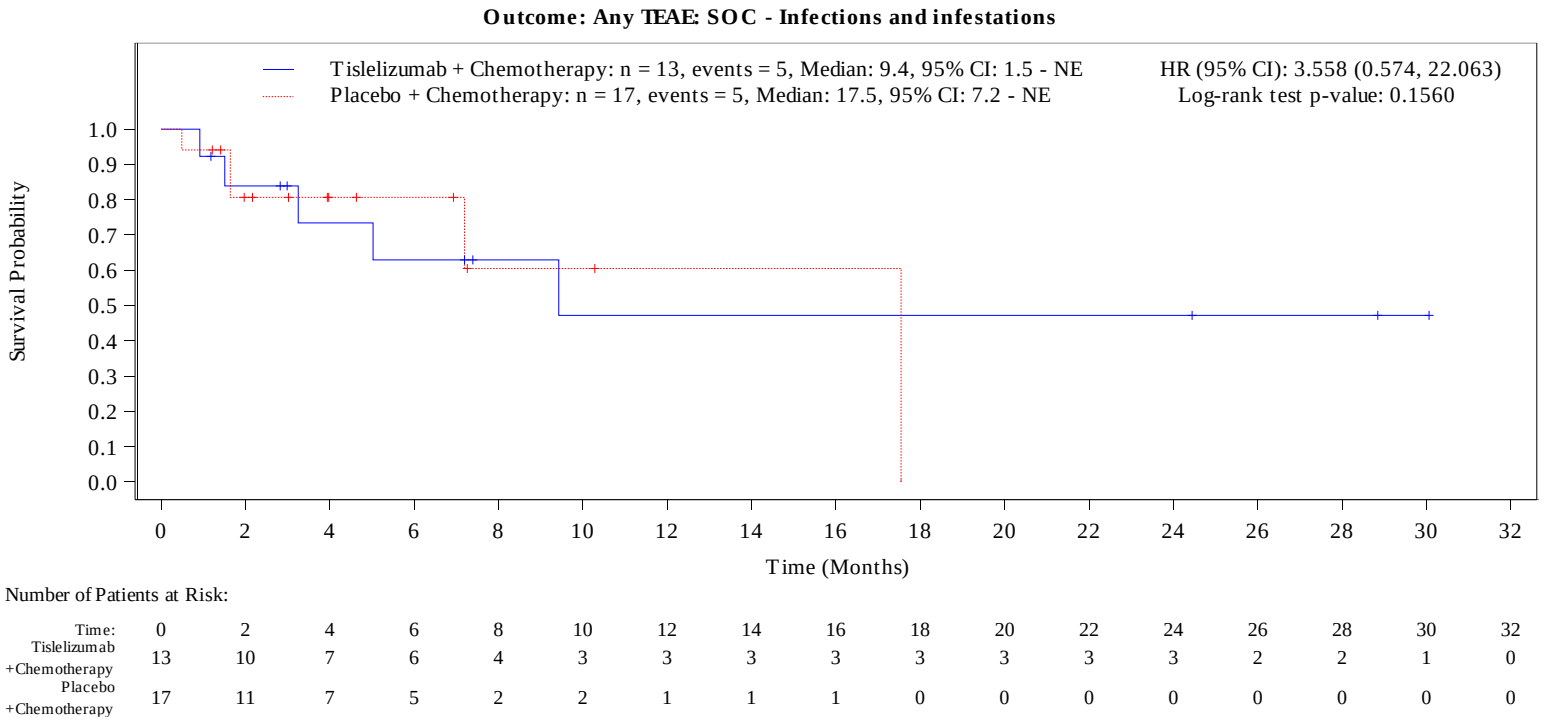

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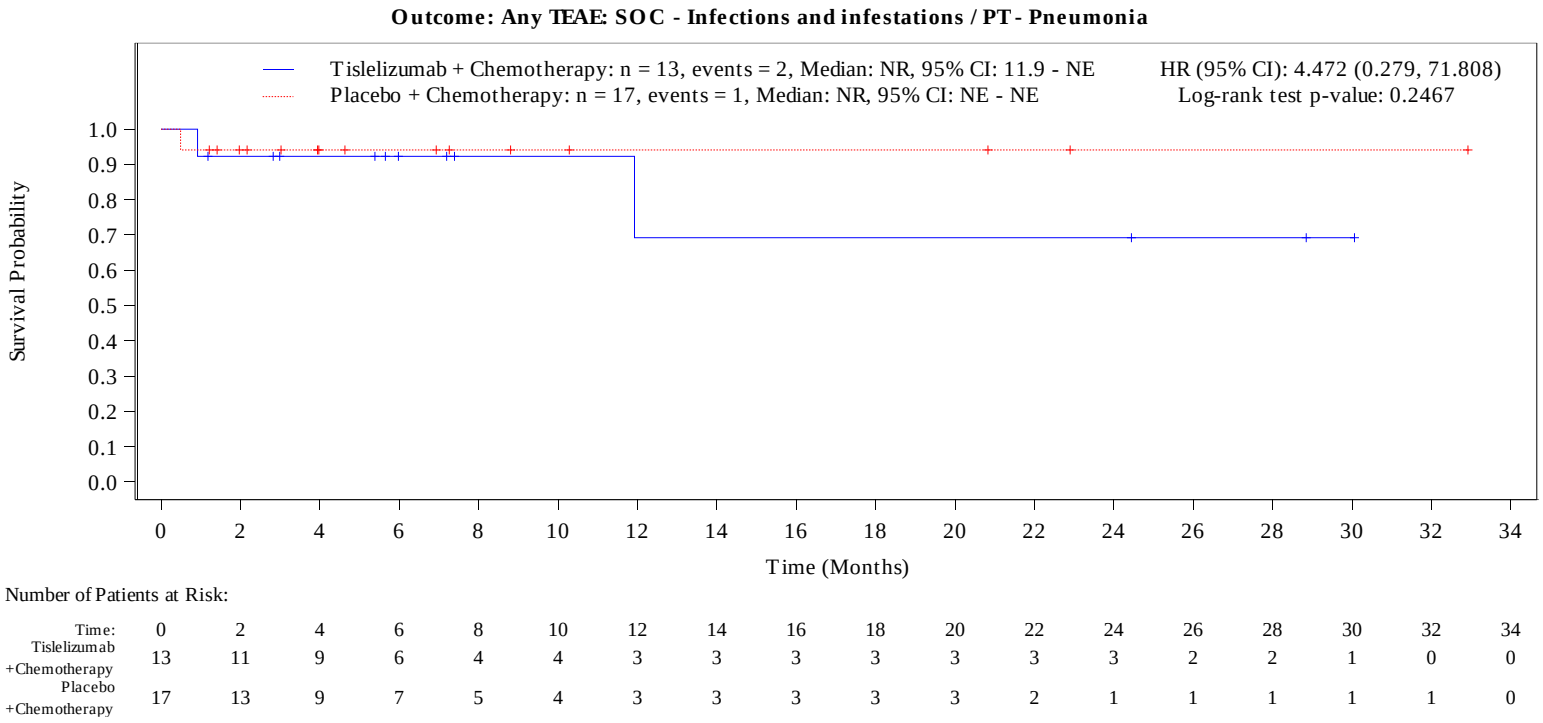

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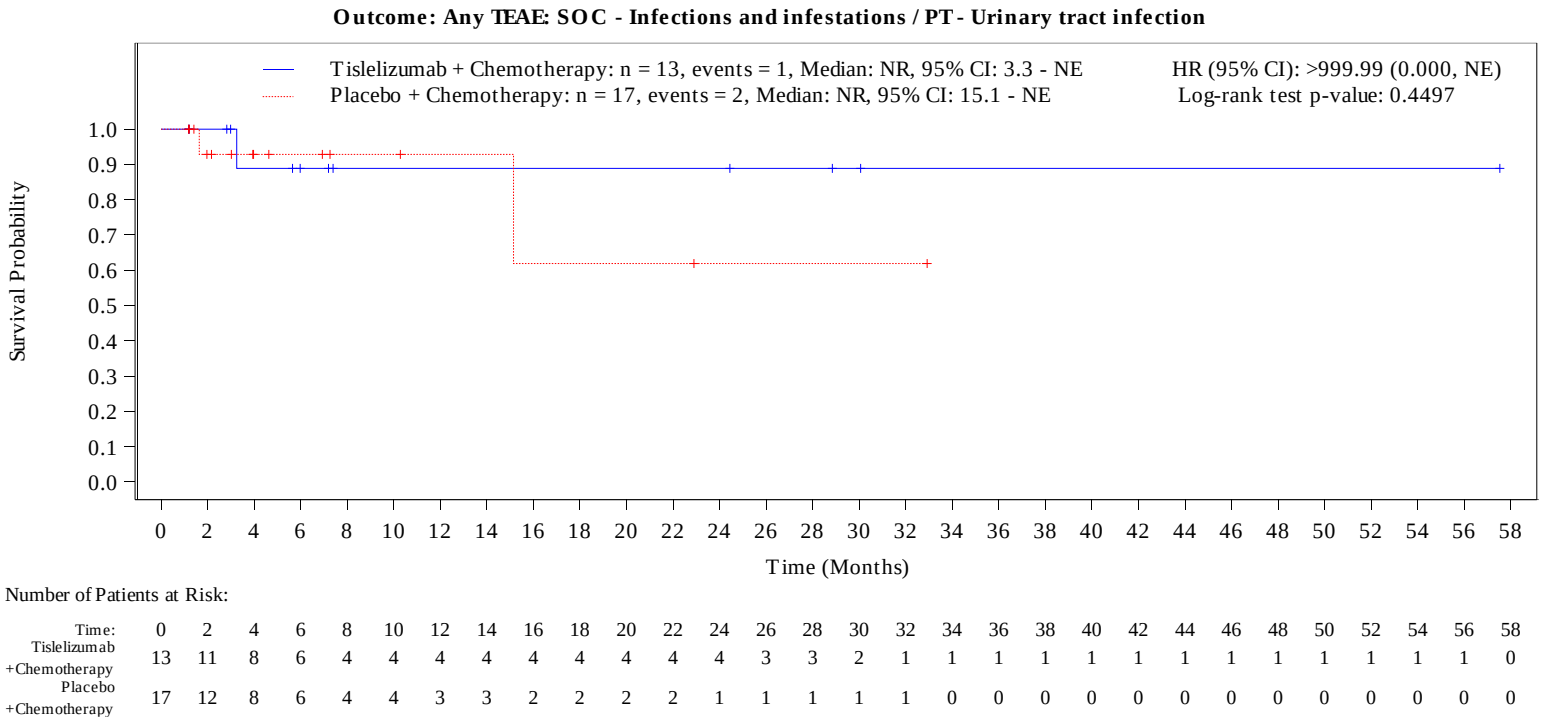

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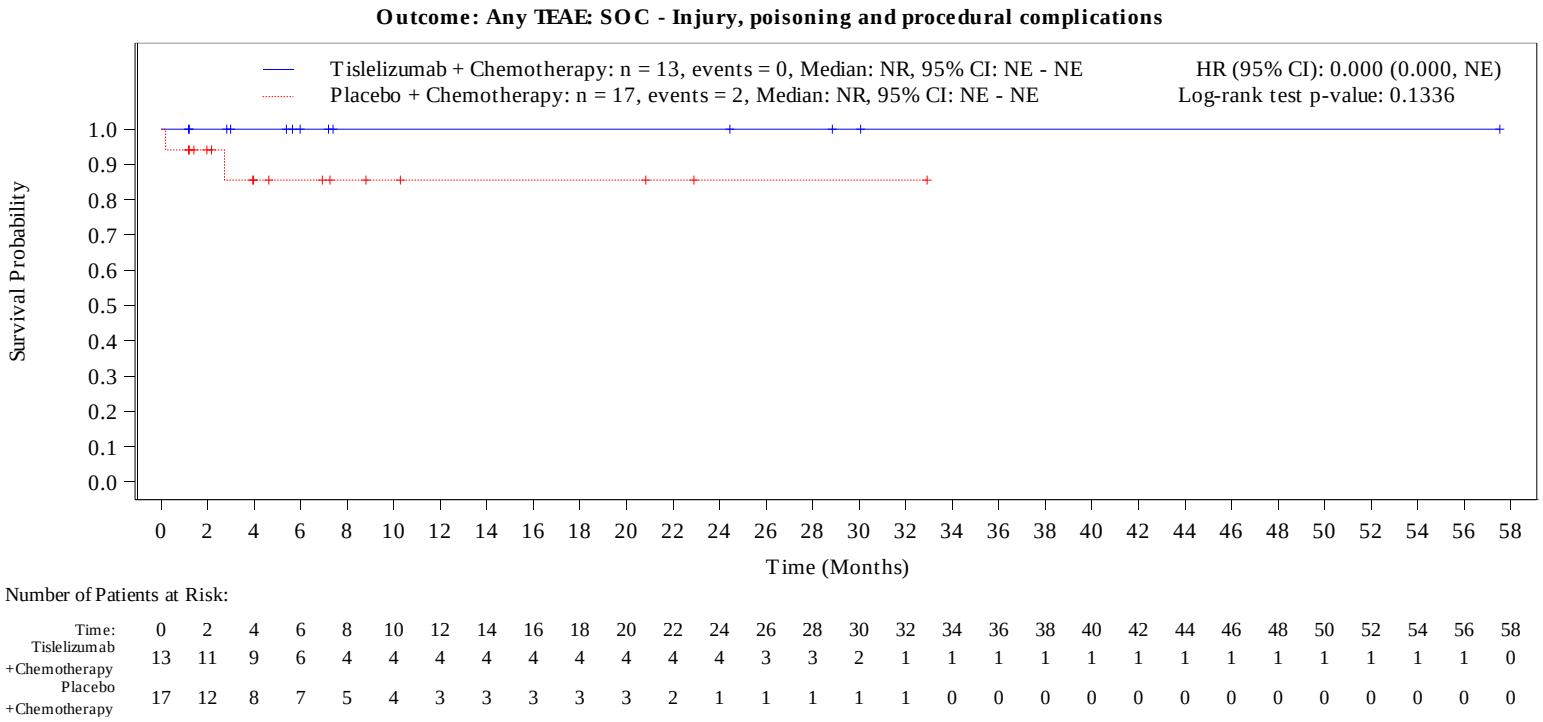
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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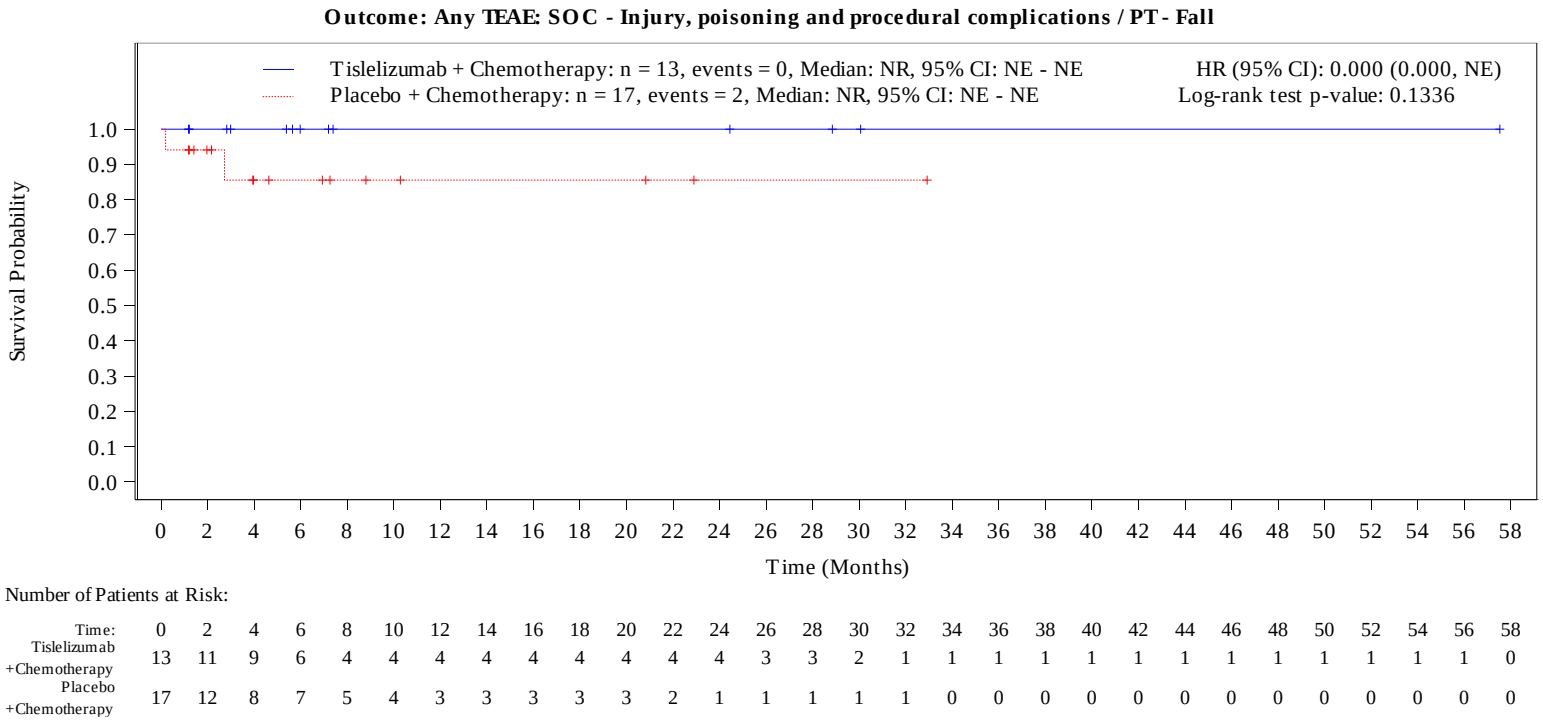
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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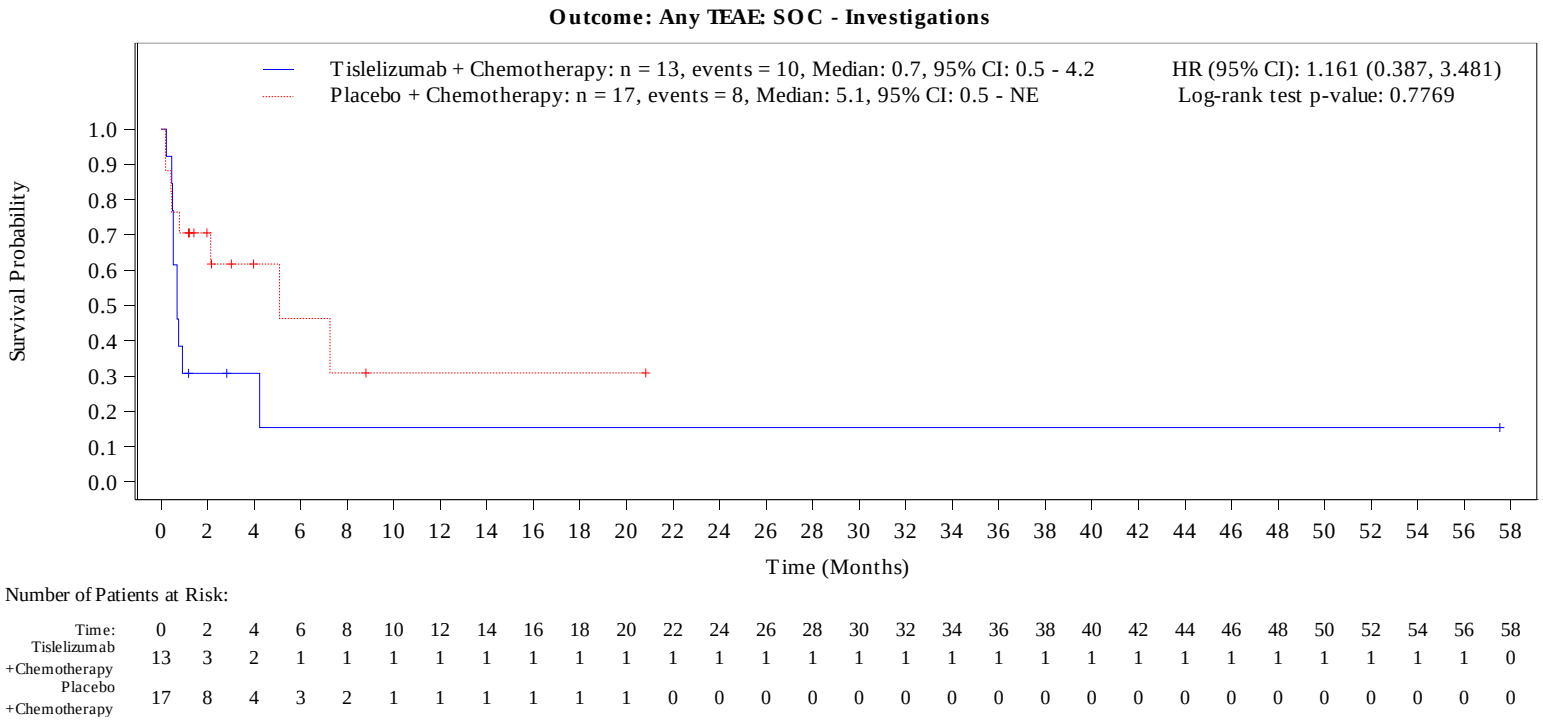
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	8	4	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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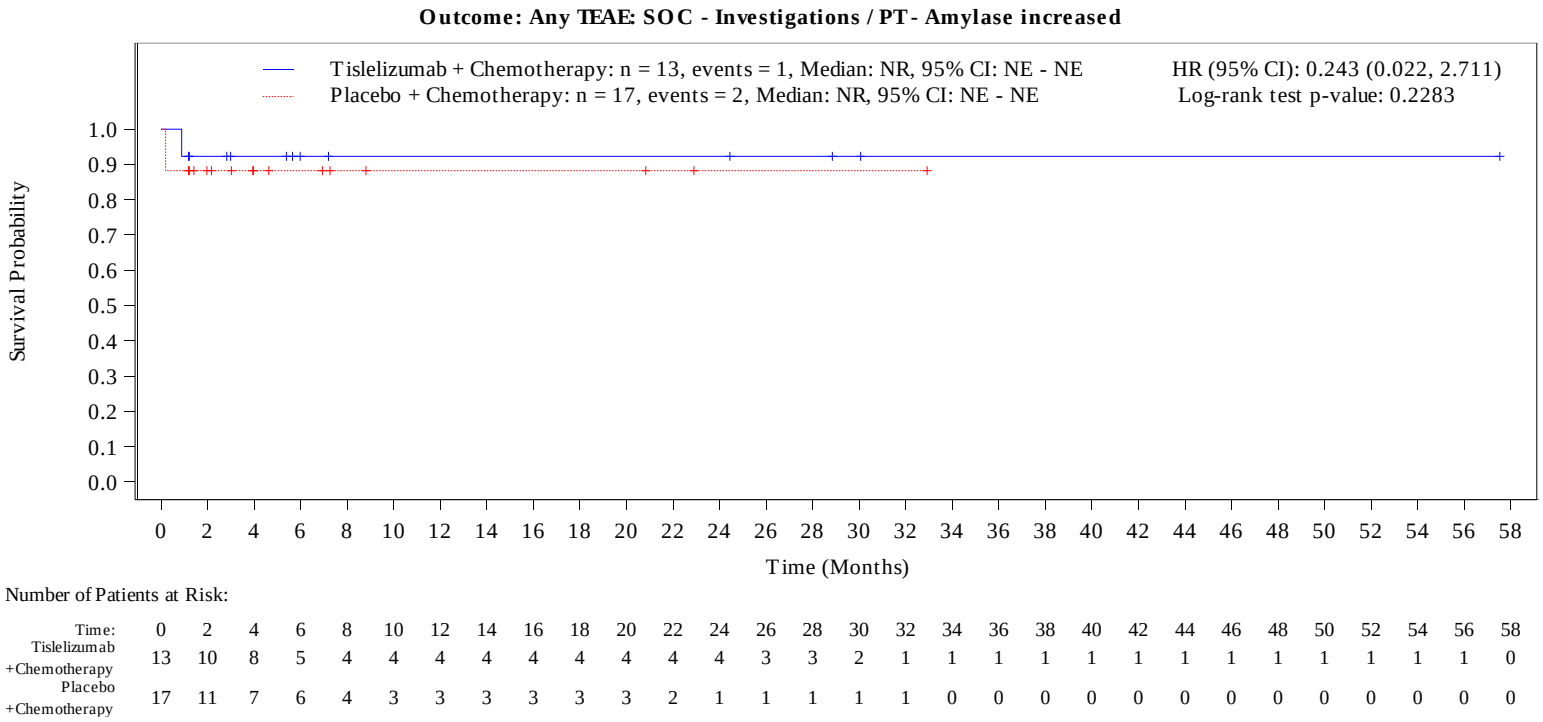
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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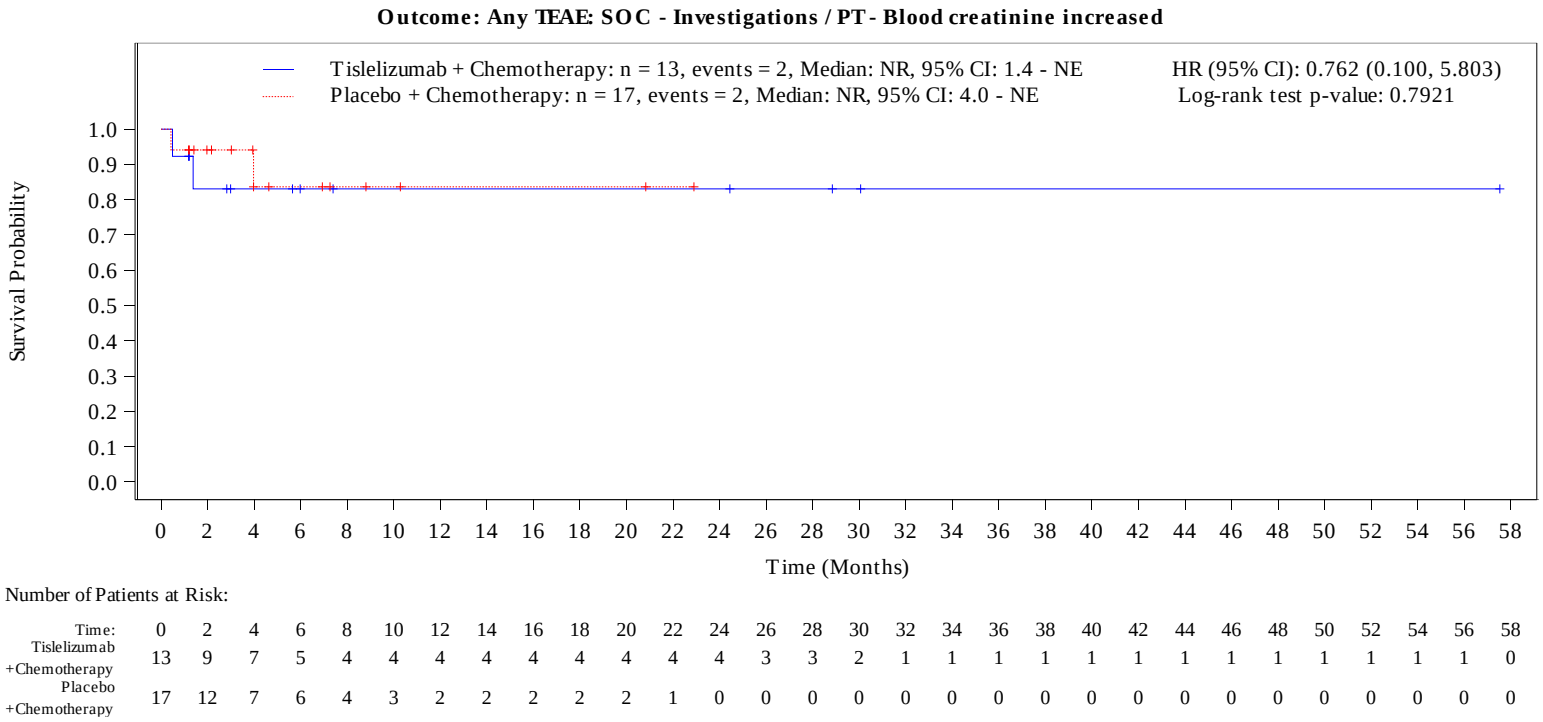
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	9	7	5	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	7	6	4	3	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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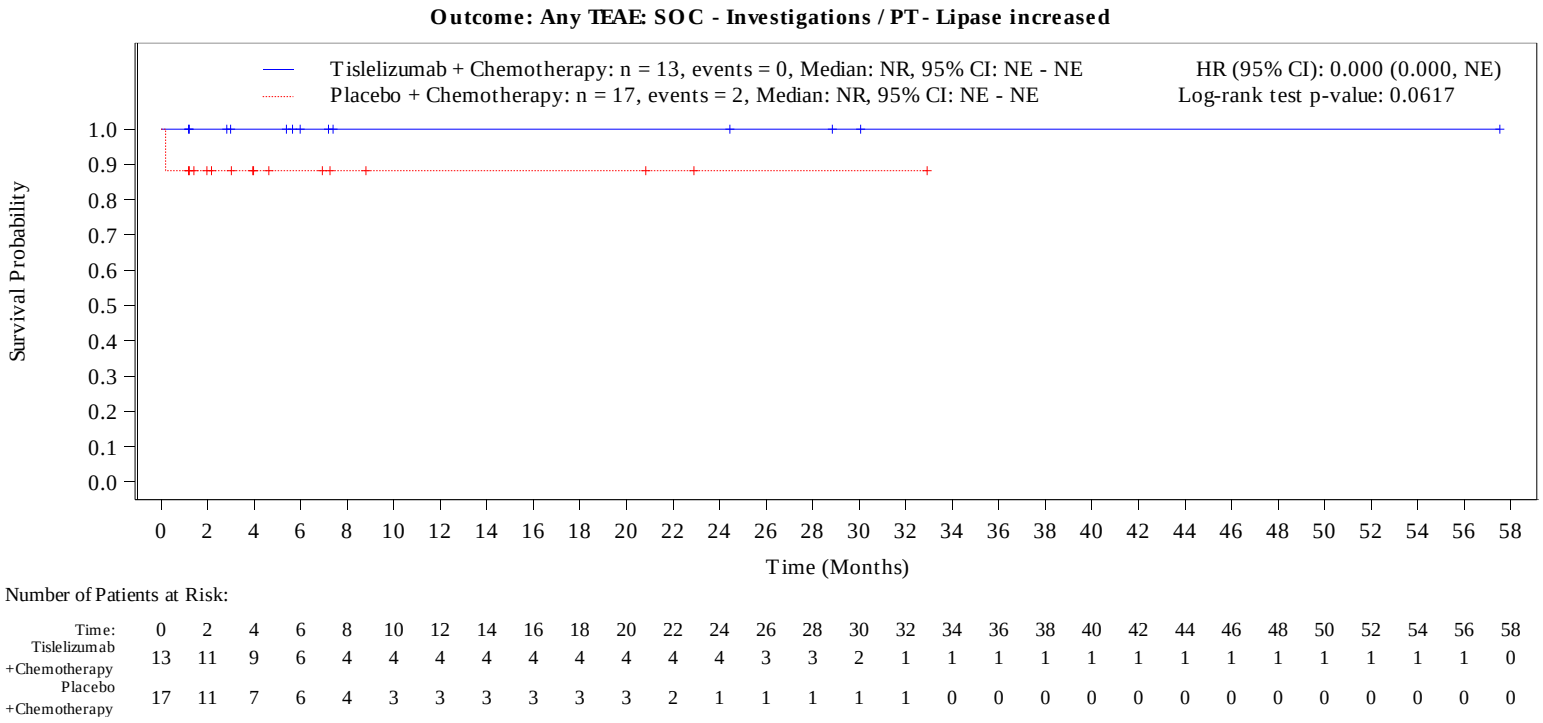
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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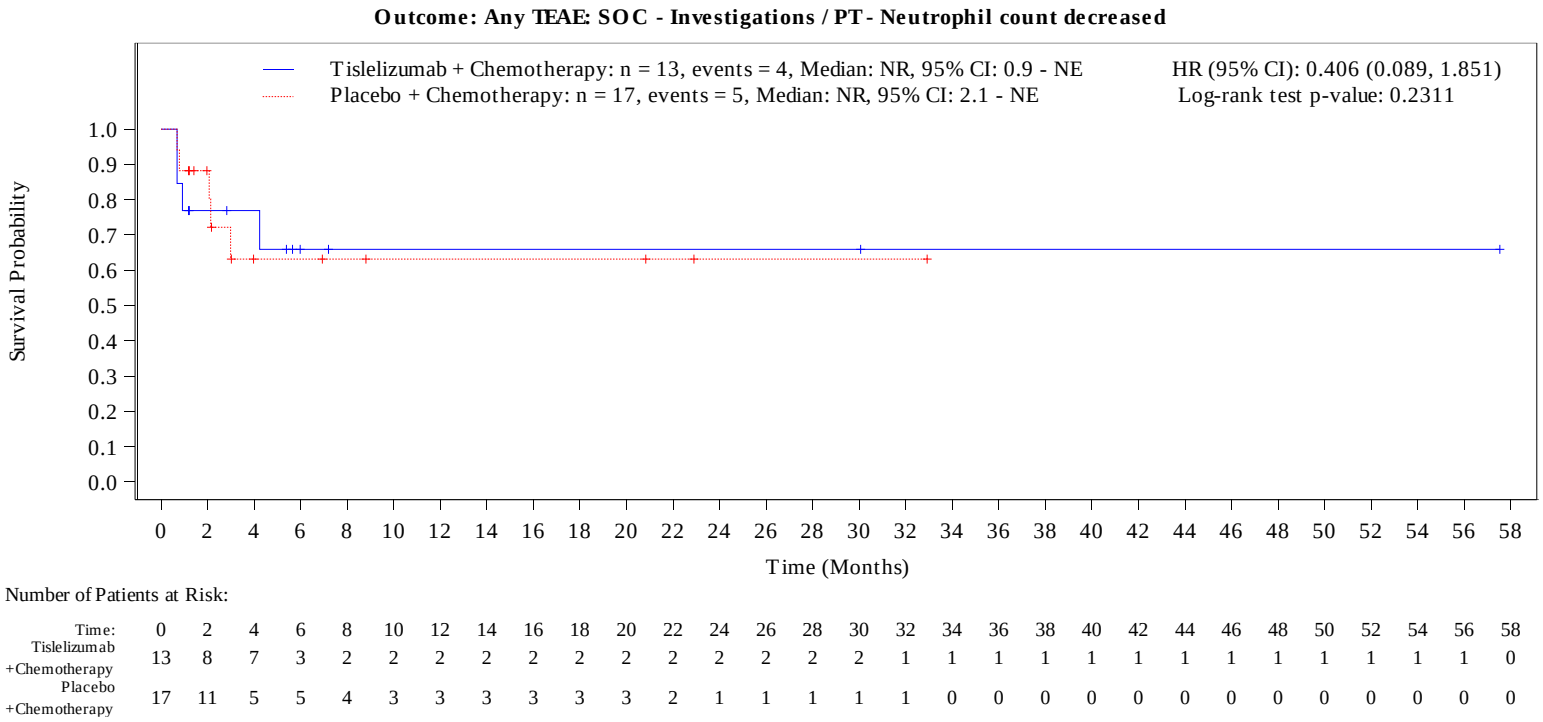
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	8	7	3	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	11	5	5	4	3	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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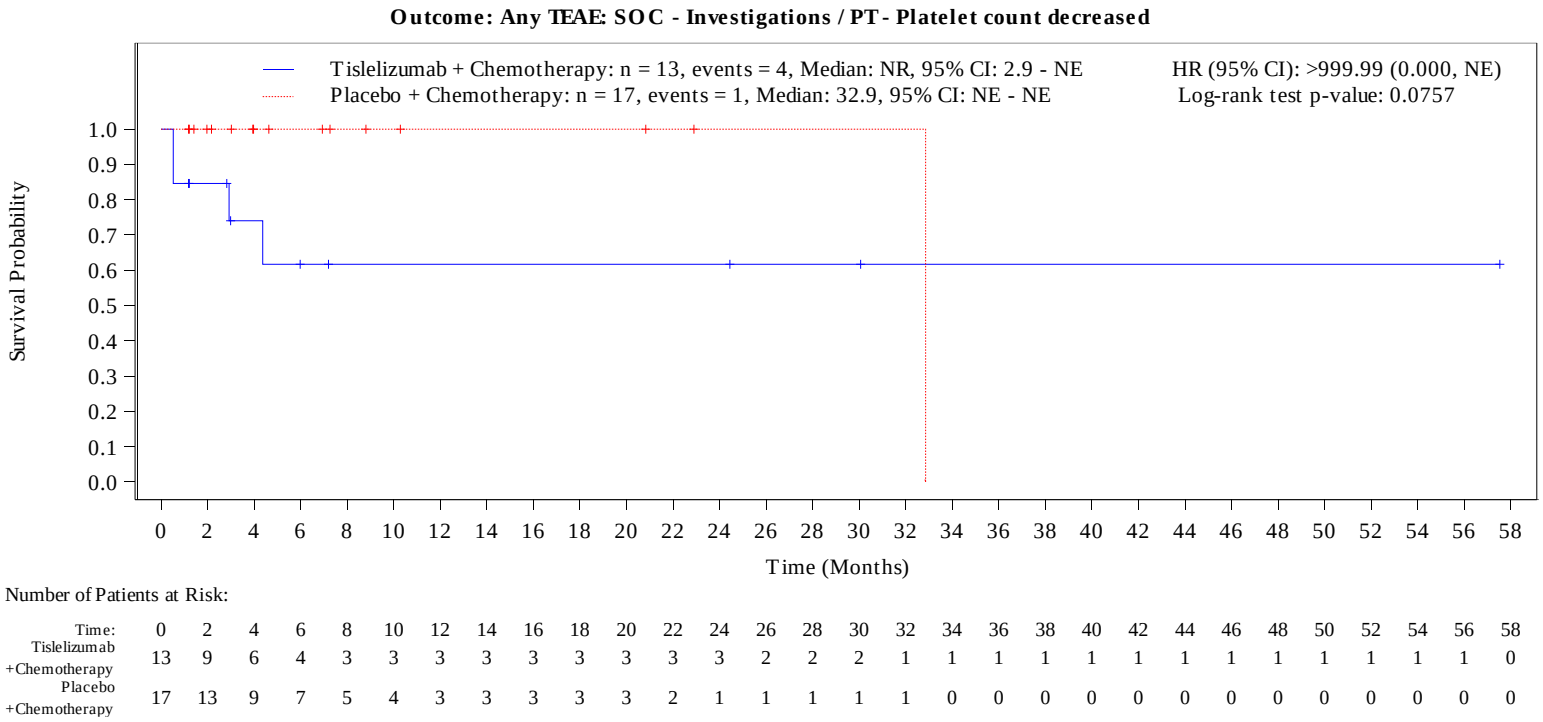
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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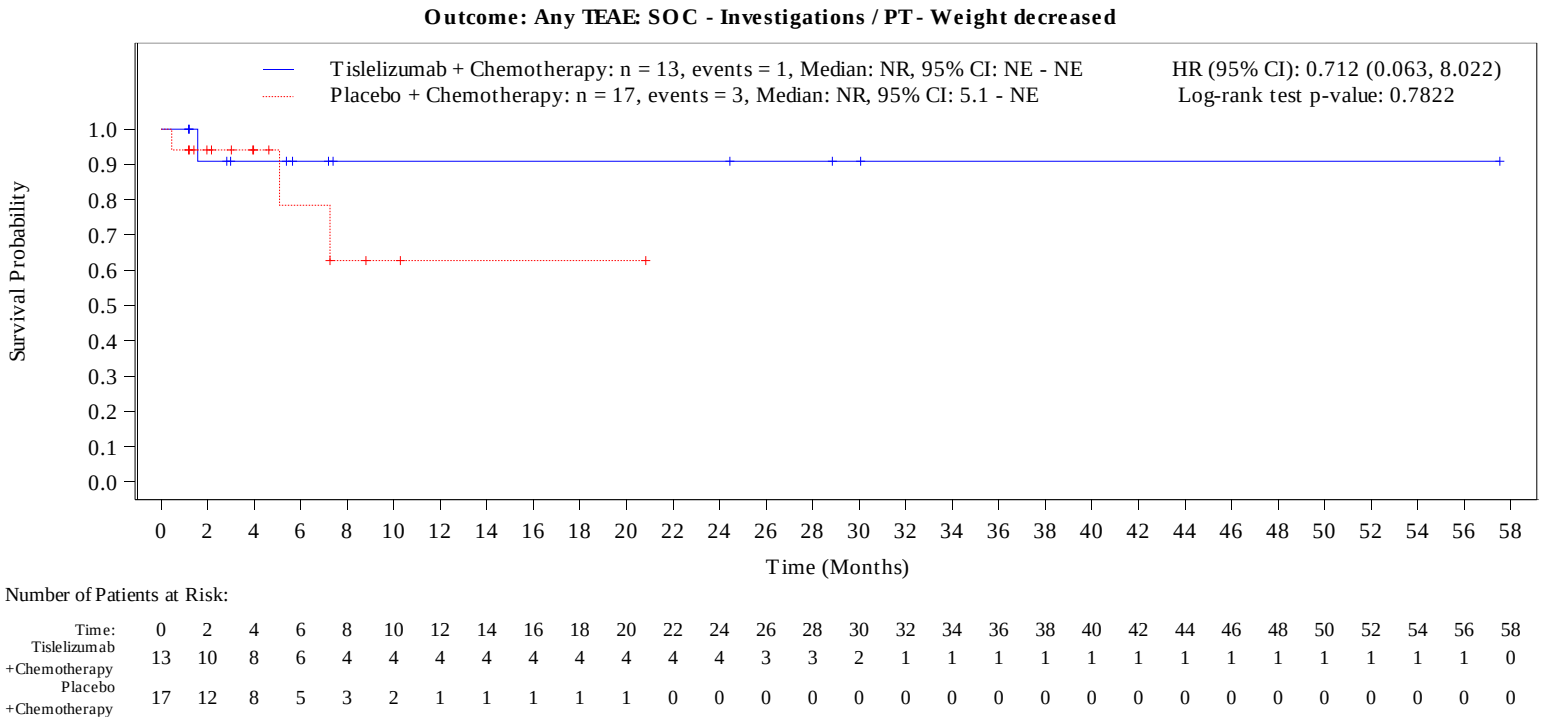
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	10	8	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	8	5	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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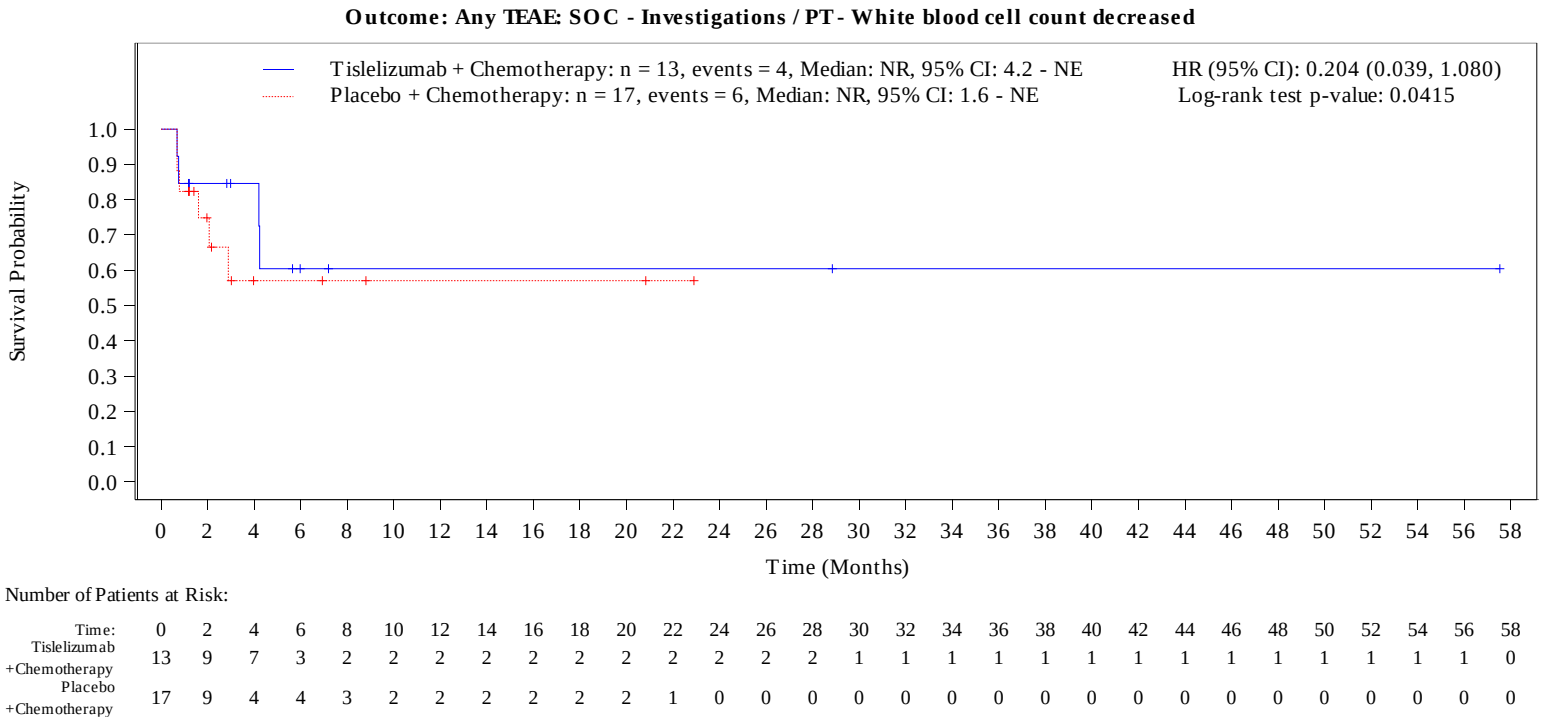
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	9	7	3	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	9	4	4	3	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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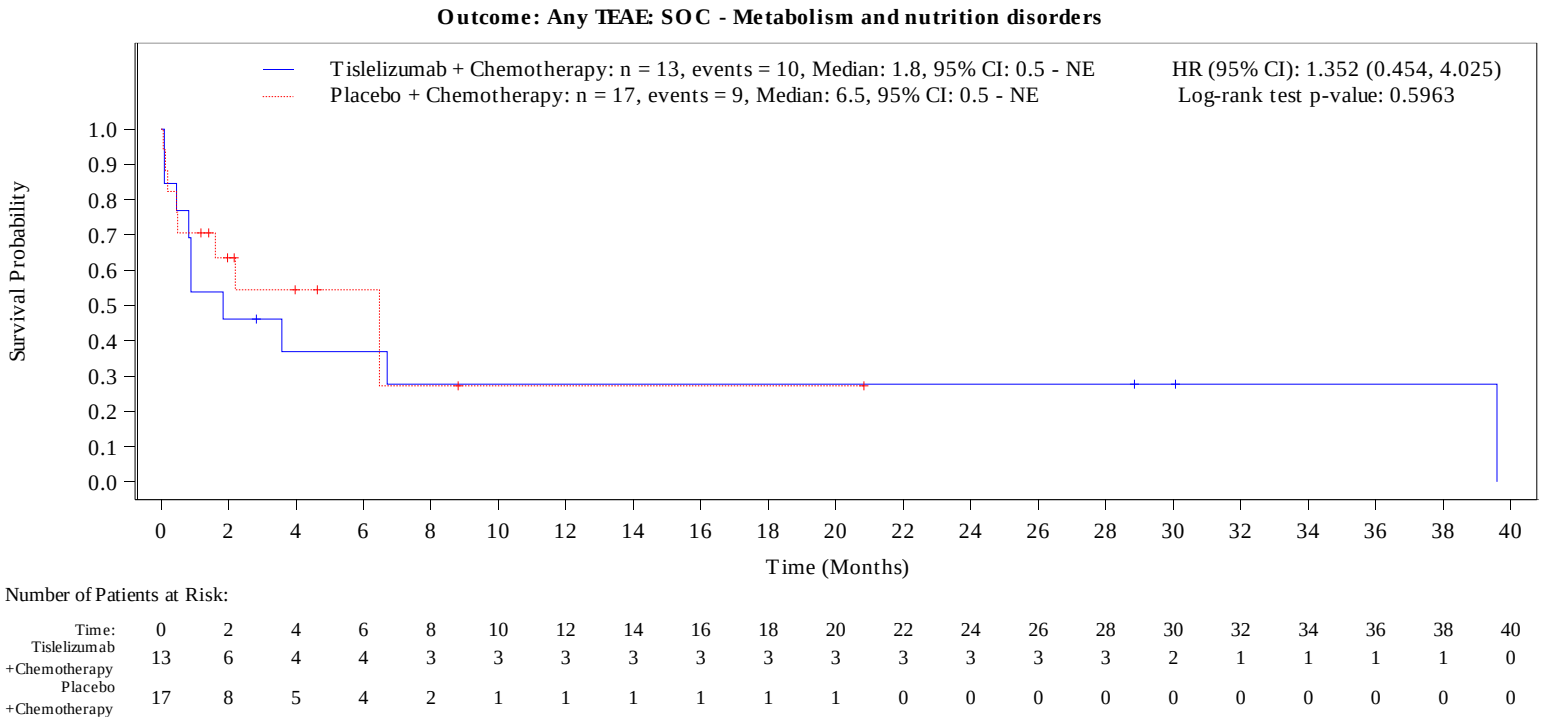
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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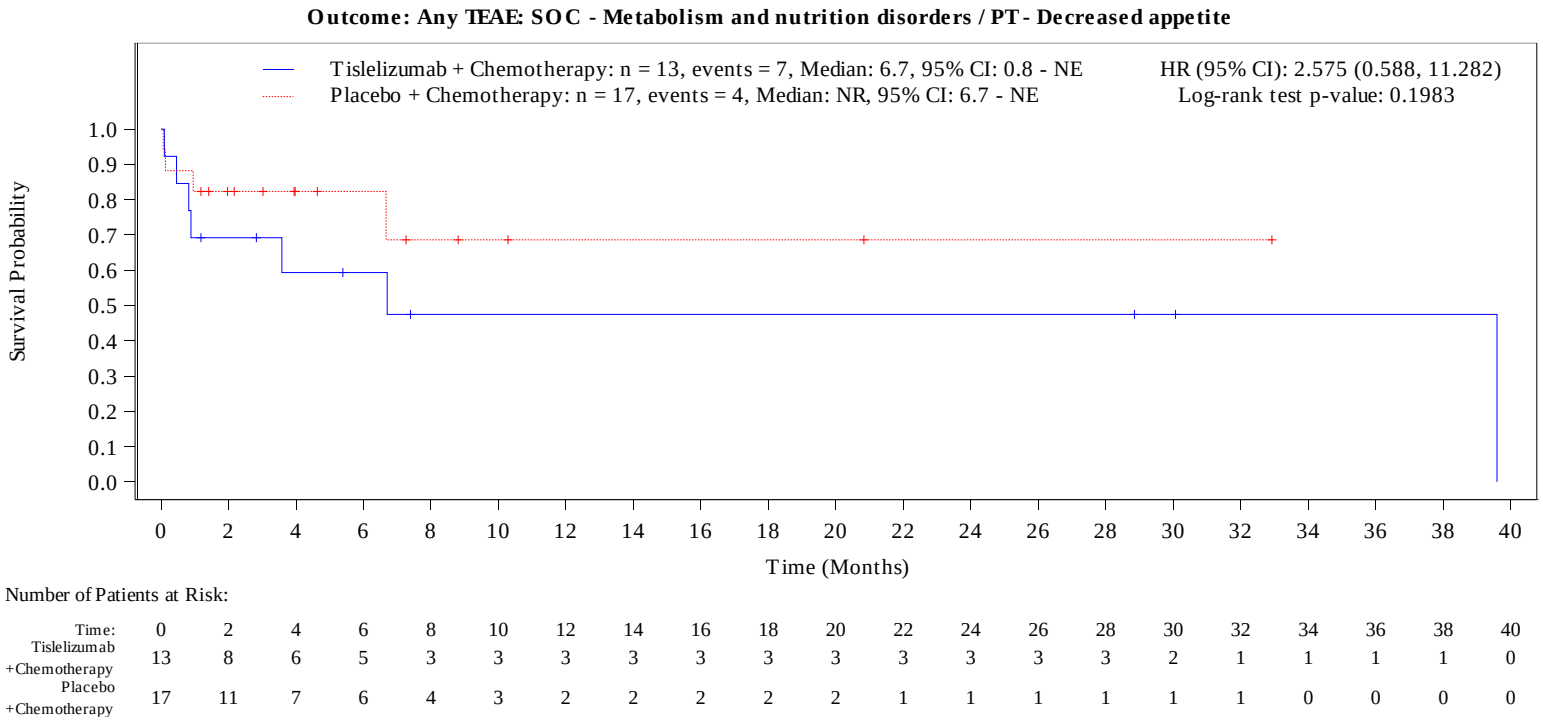
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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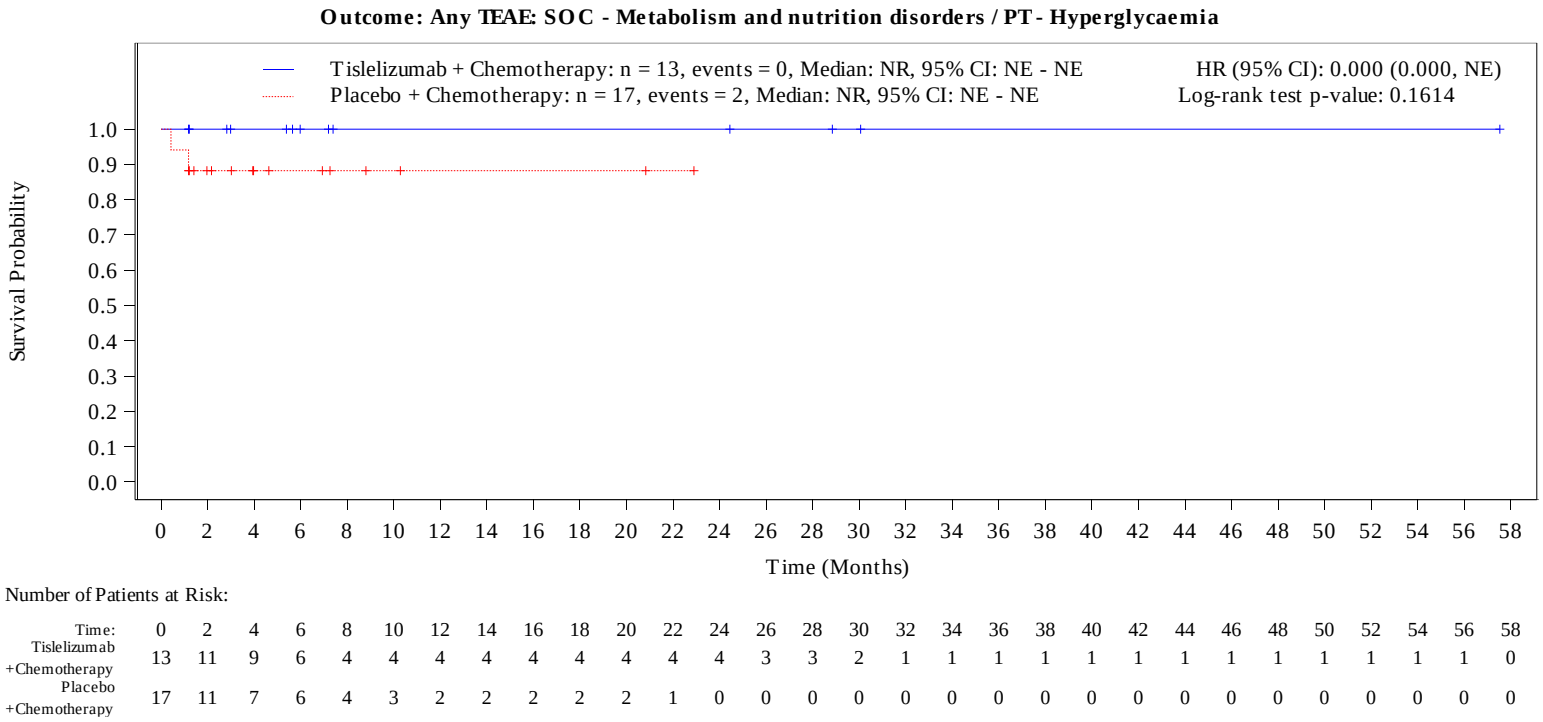
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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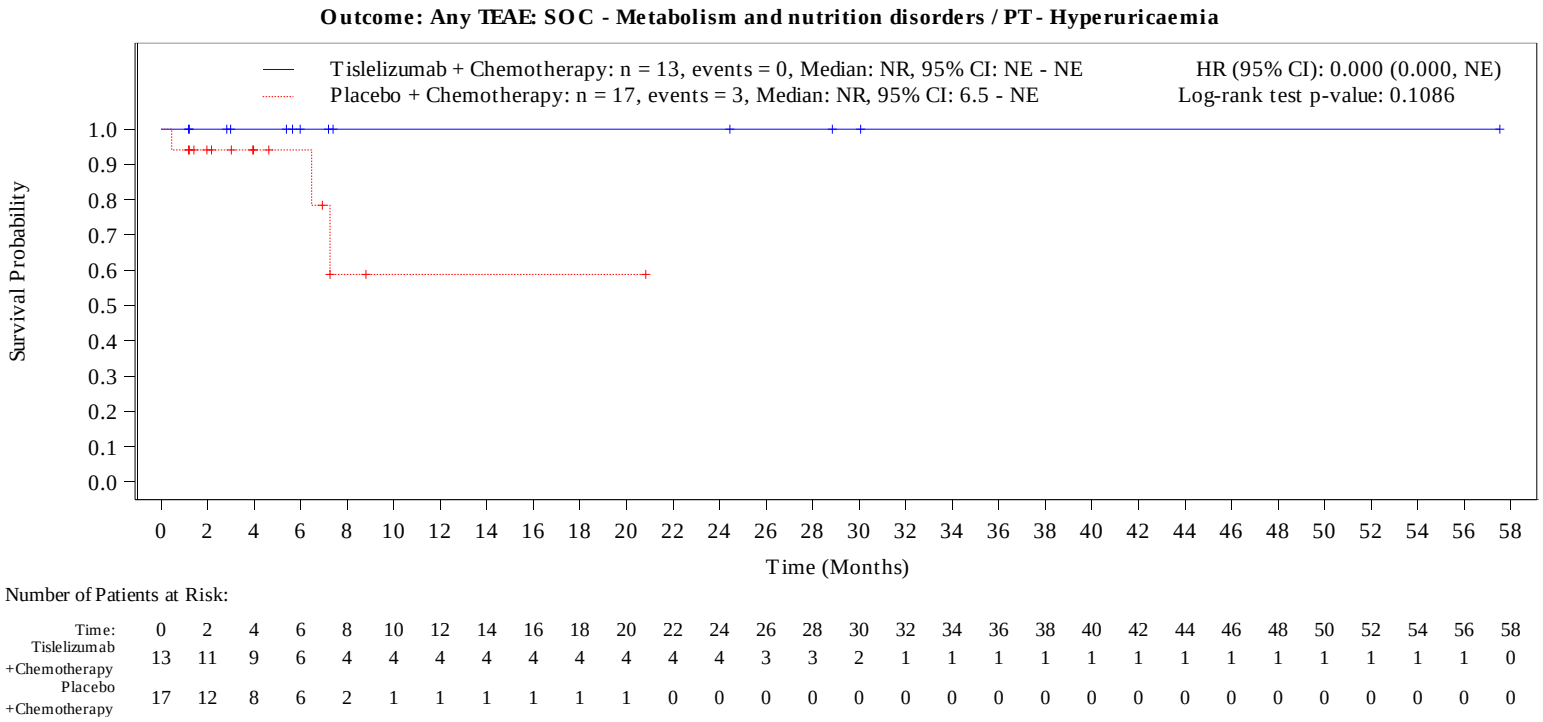

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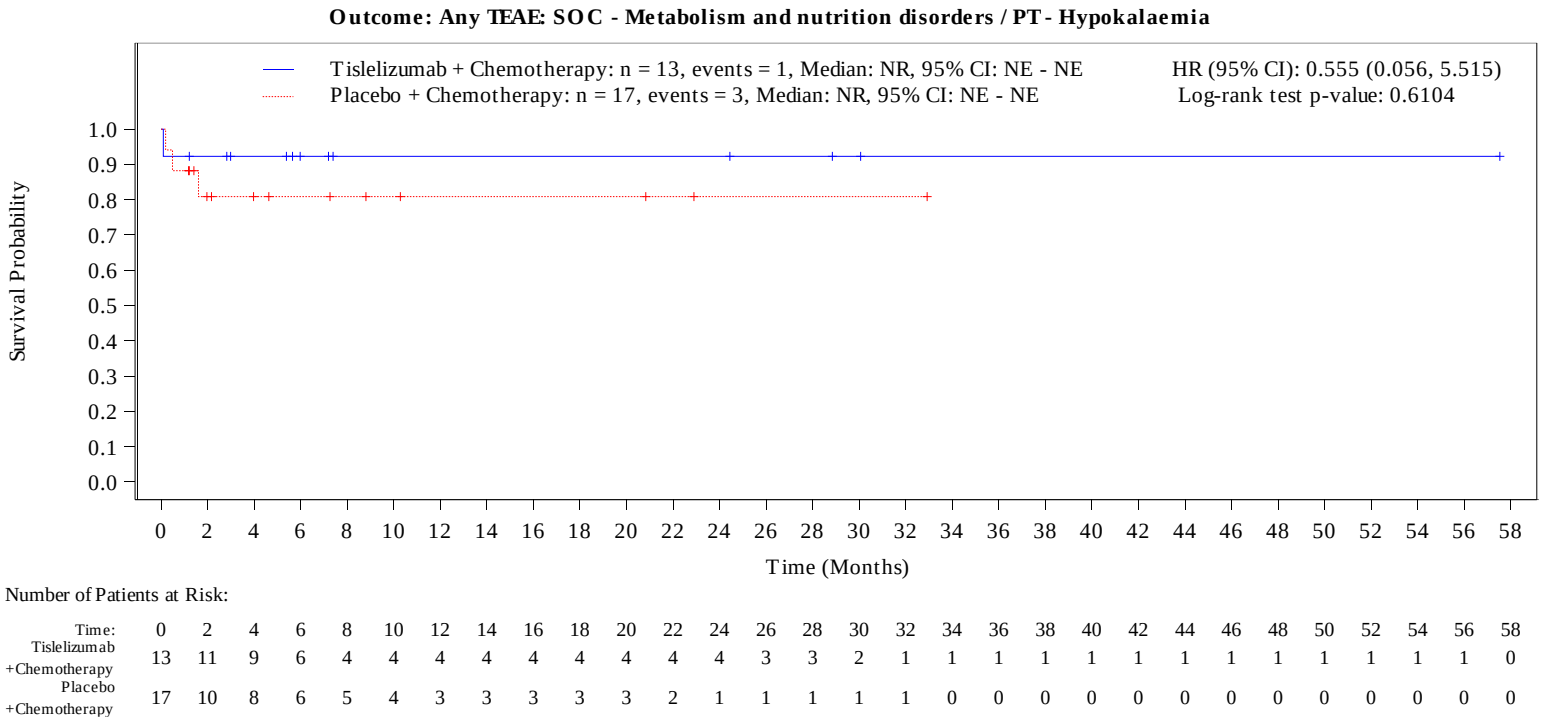

Number of Patients at Risk:

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Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	10	8	6	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
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Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

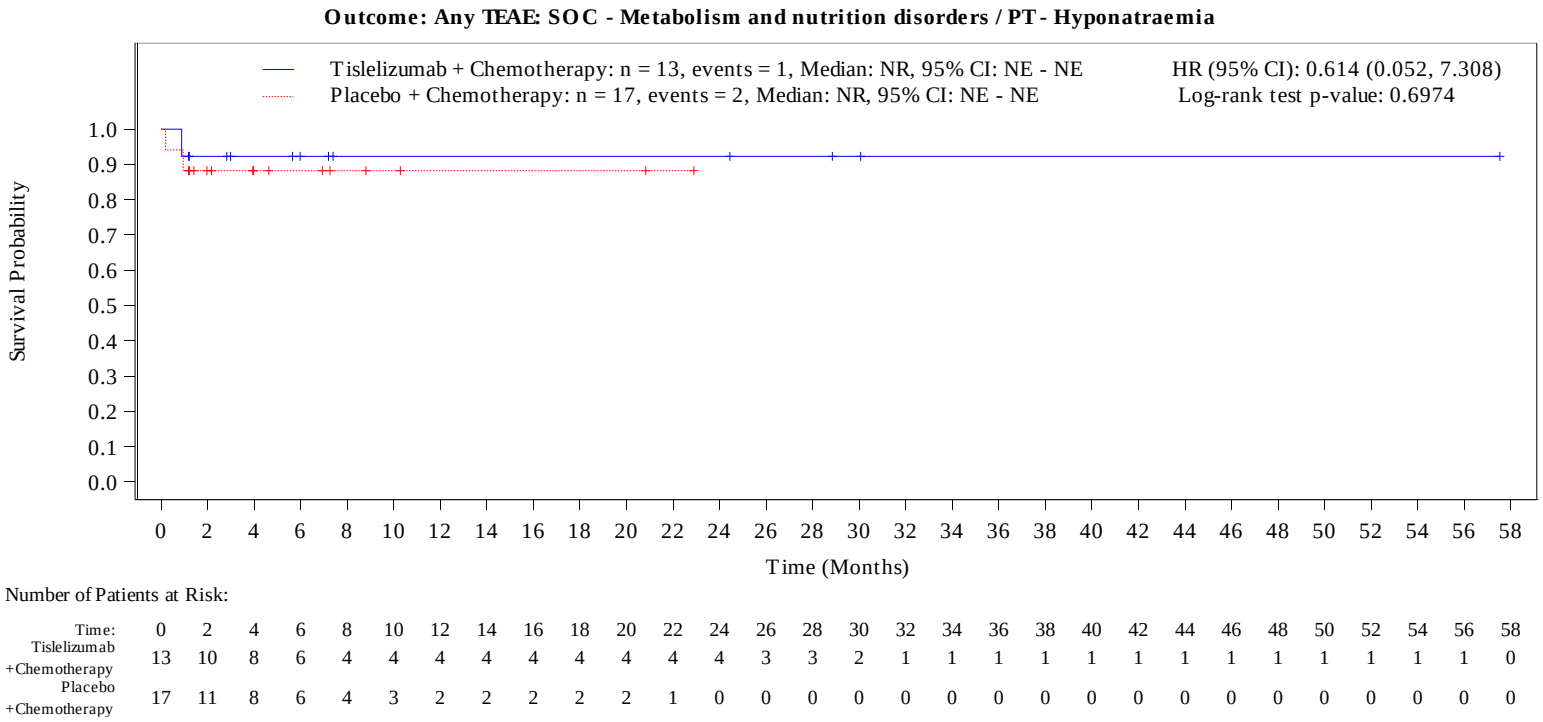

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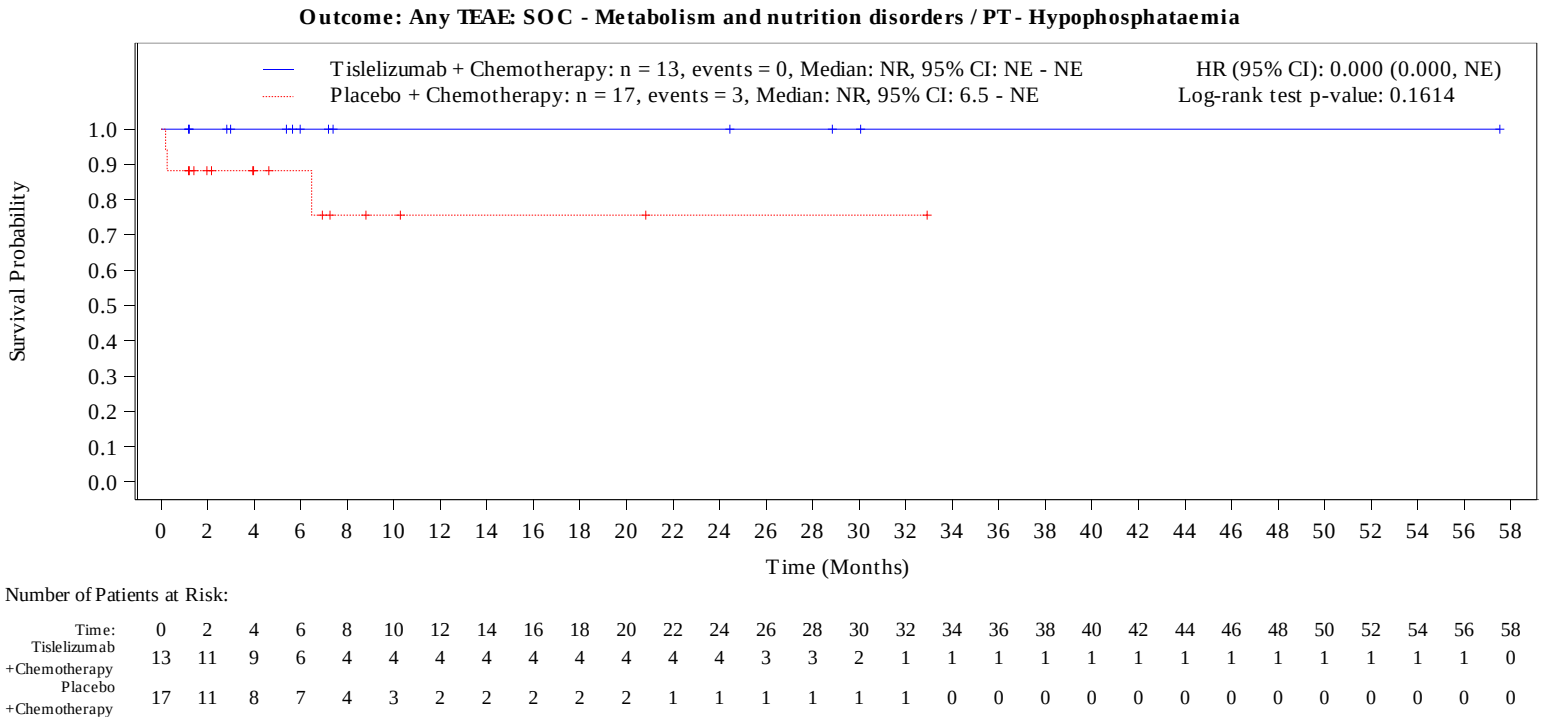
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.3.1.2:
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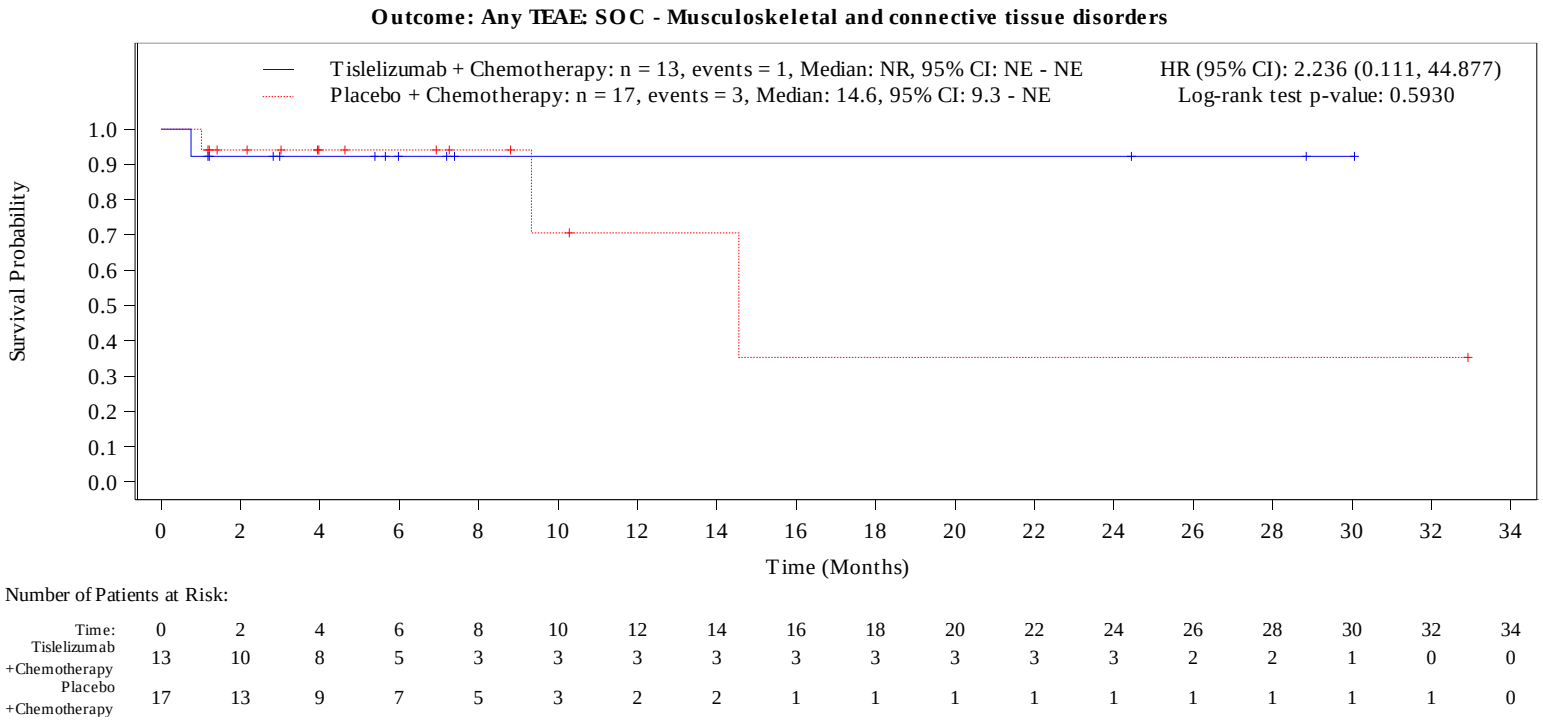

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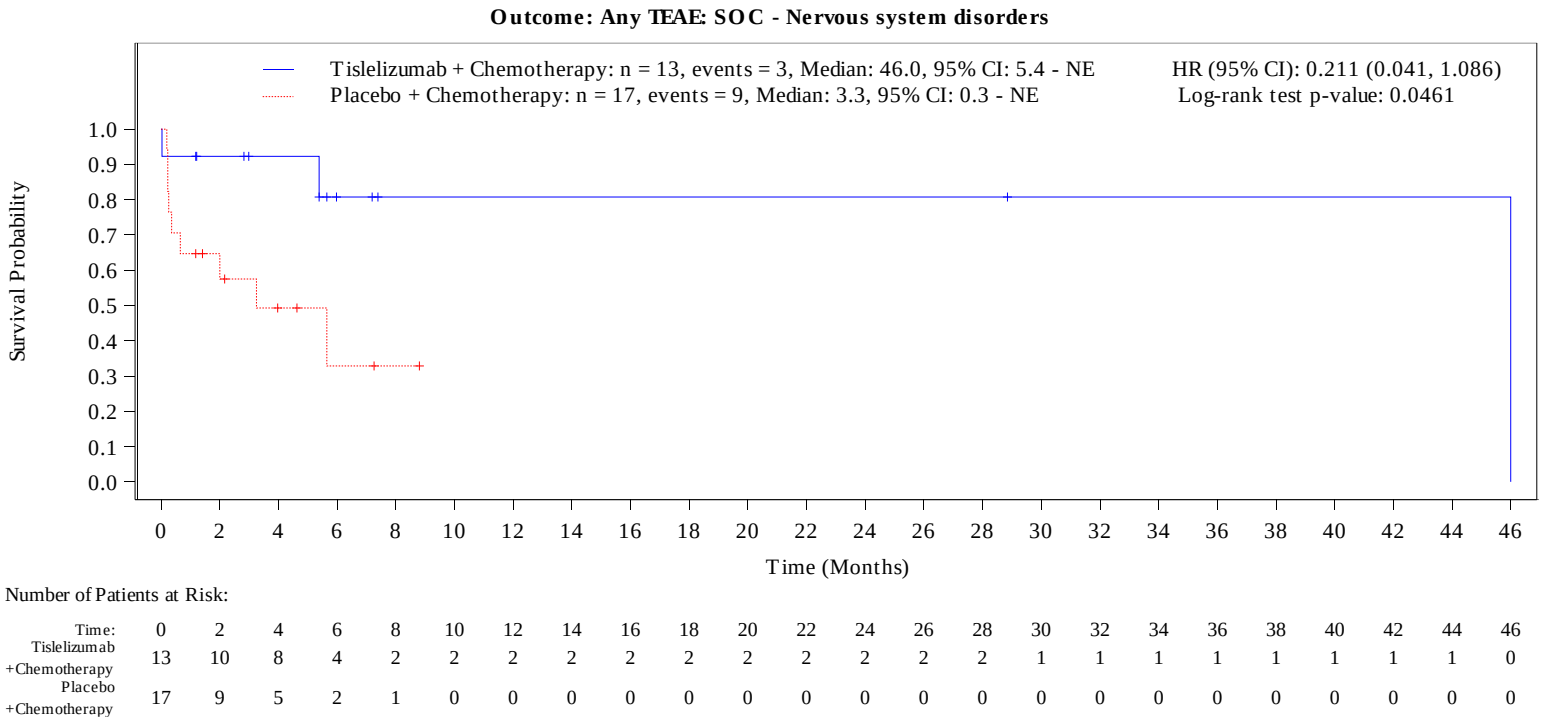

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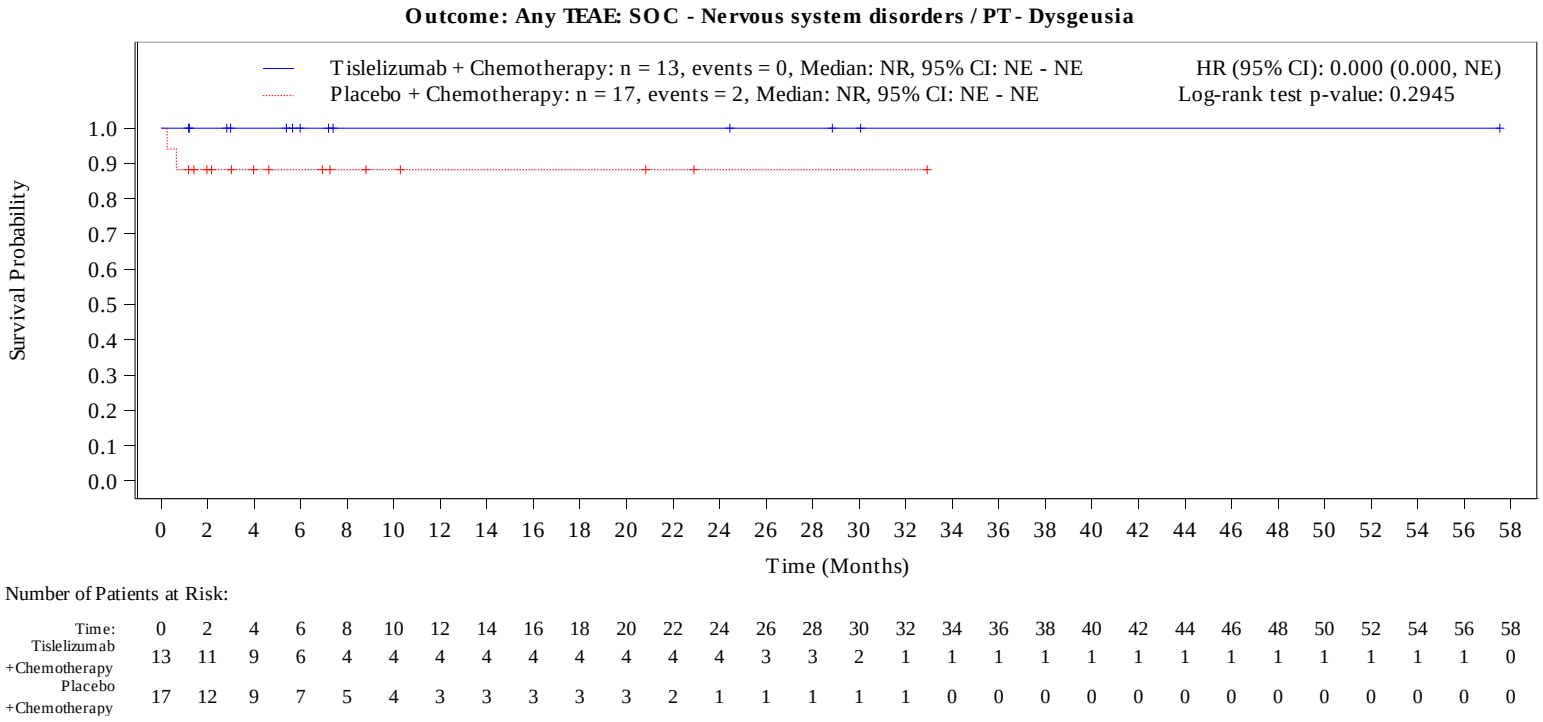

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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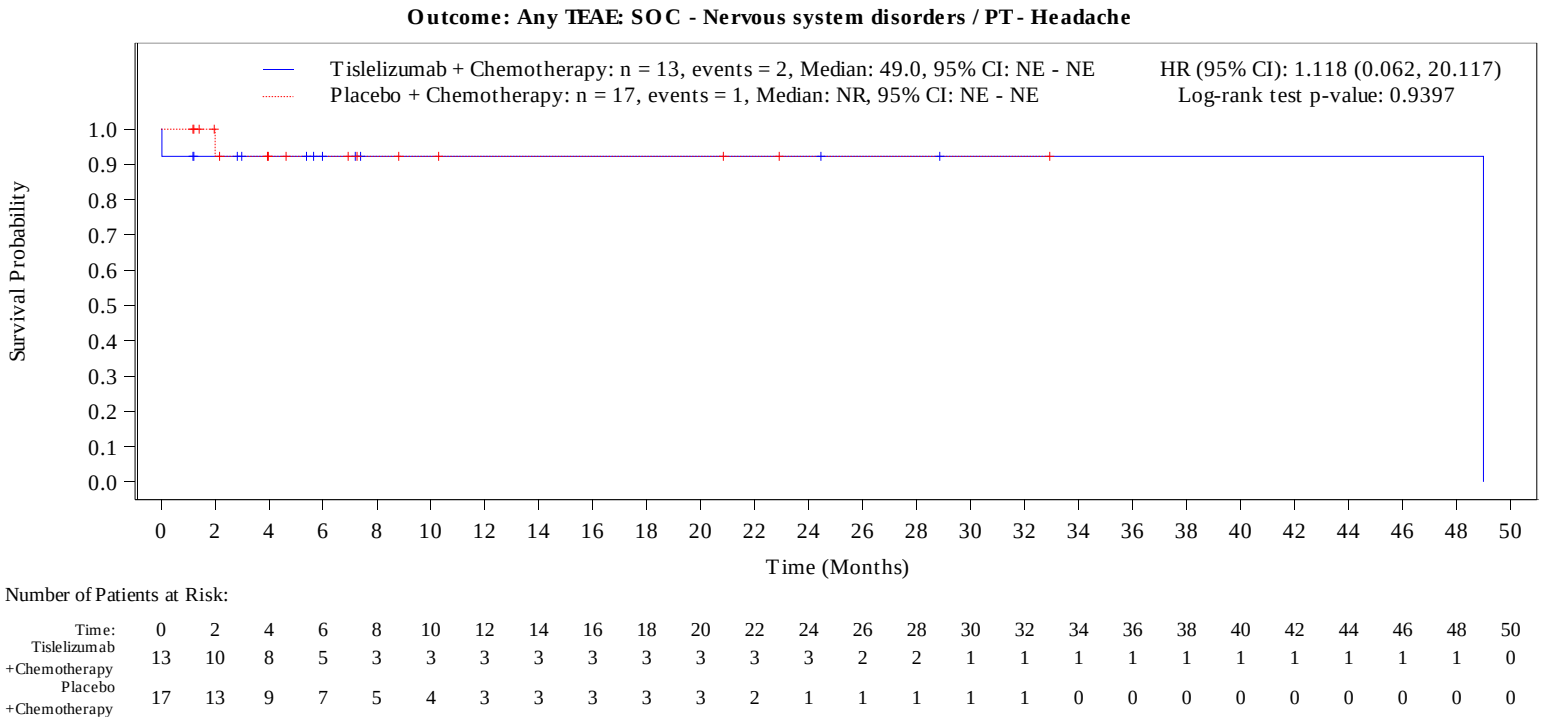
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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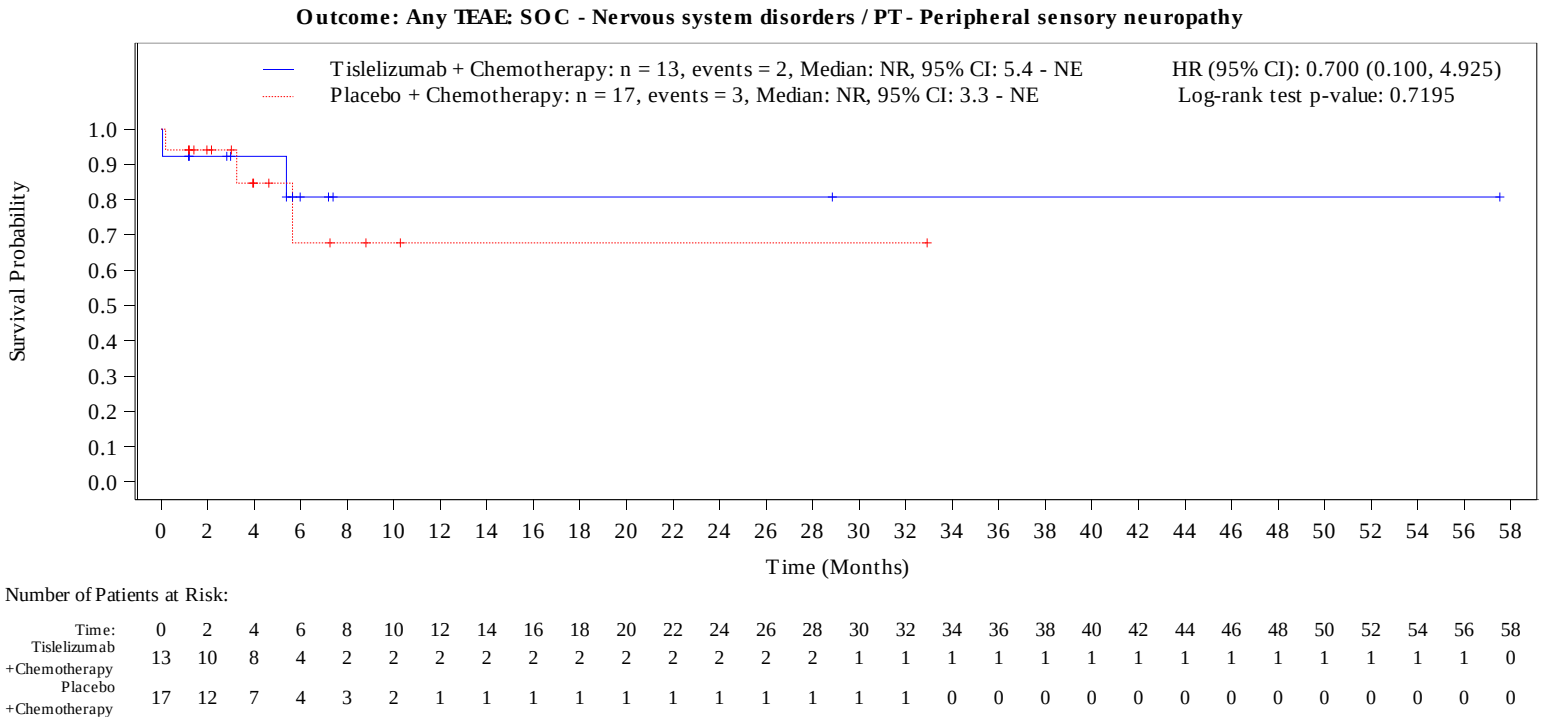

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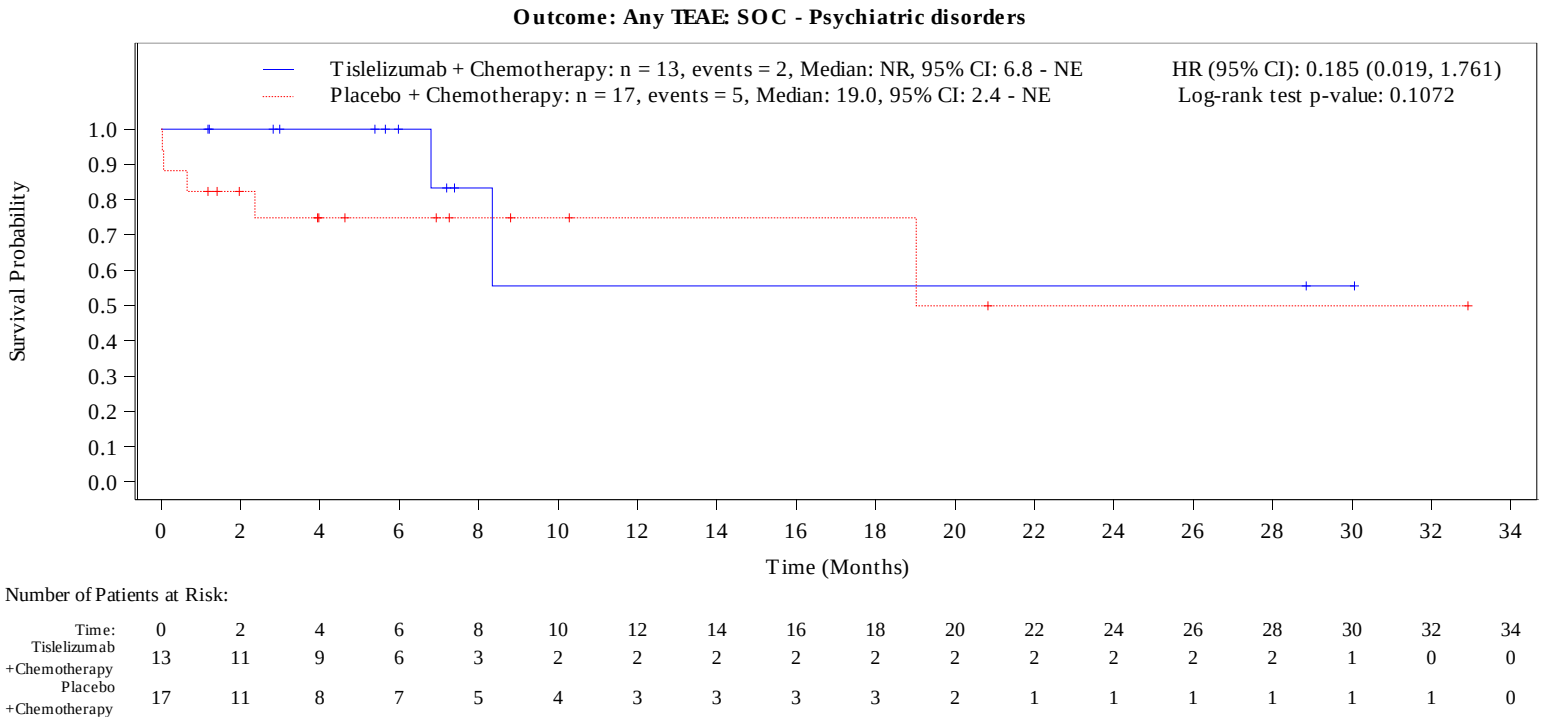

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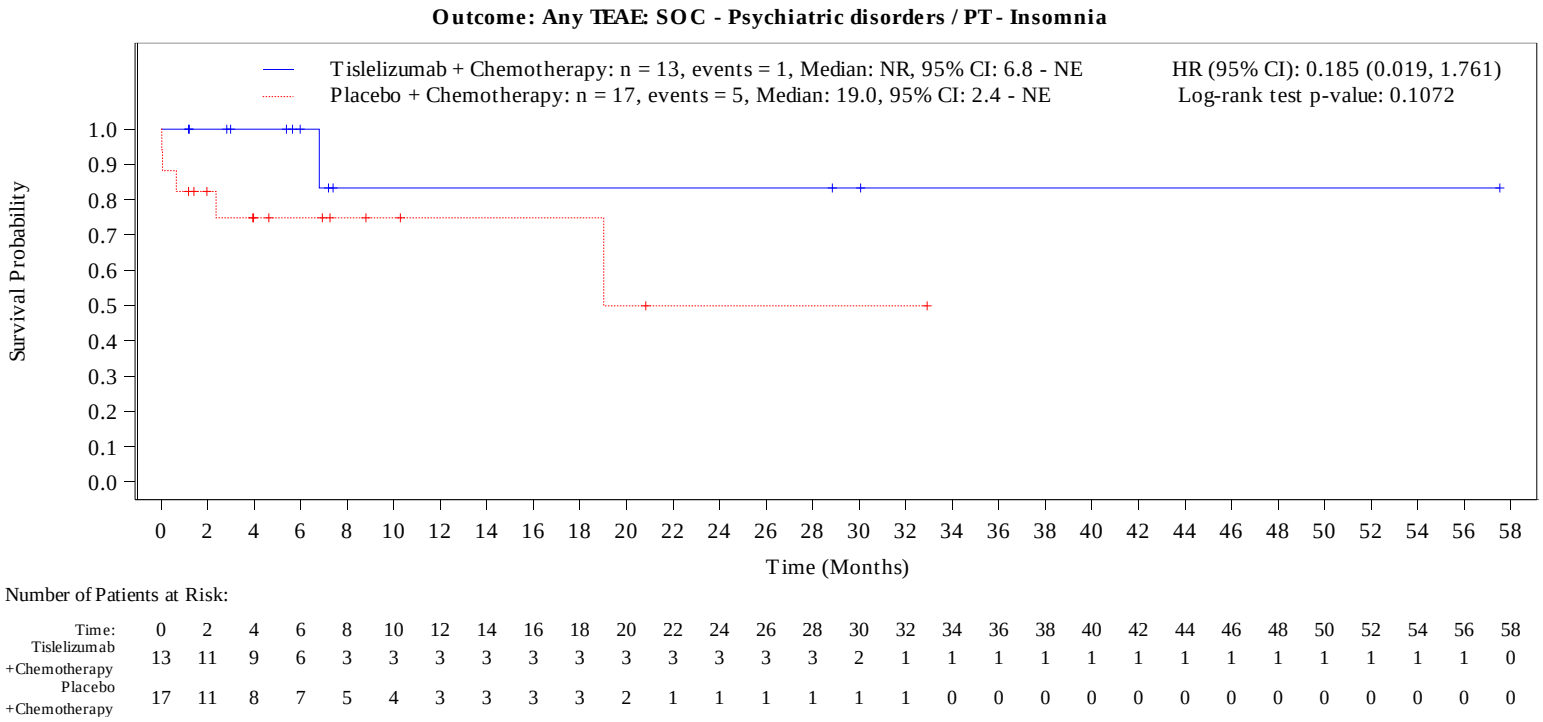

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Placebo +Chemotherapy	17	11	8	7	5	4	3	3	3	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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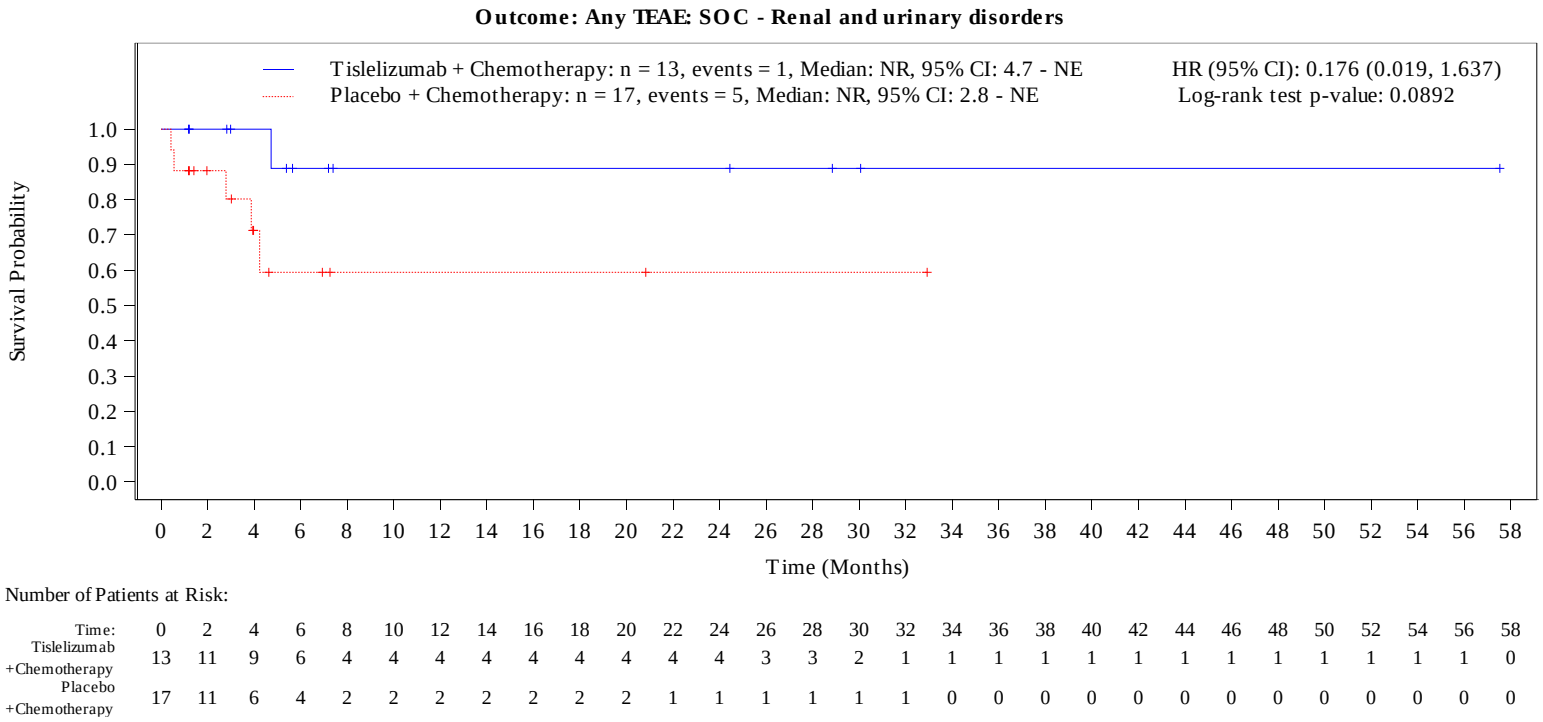
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
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Placebo +Chemotherapy	17	11	6	4	2	2	2	2	2	2	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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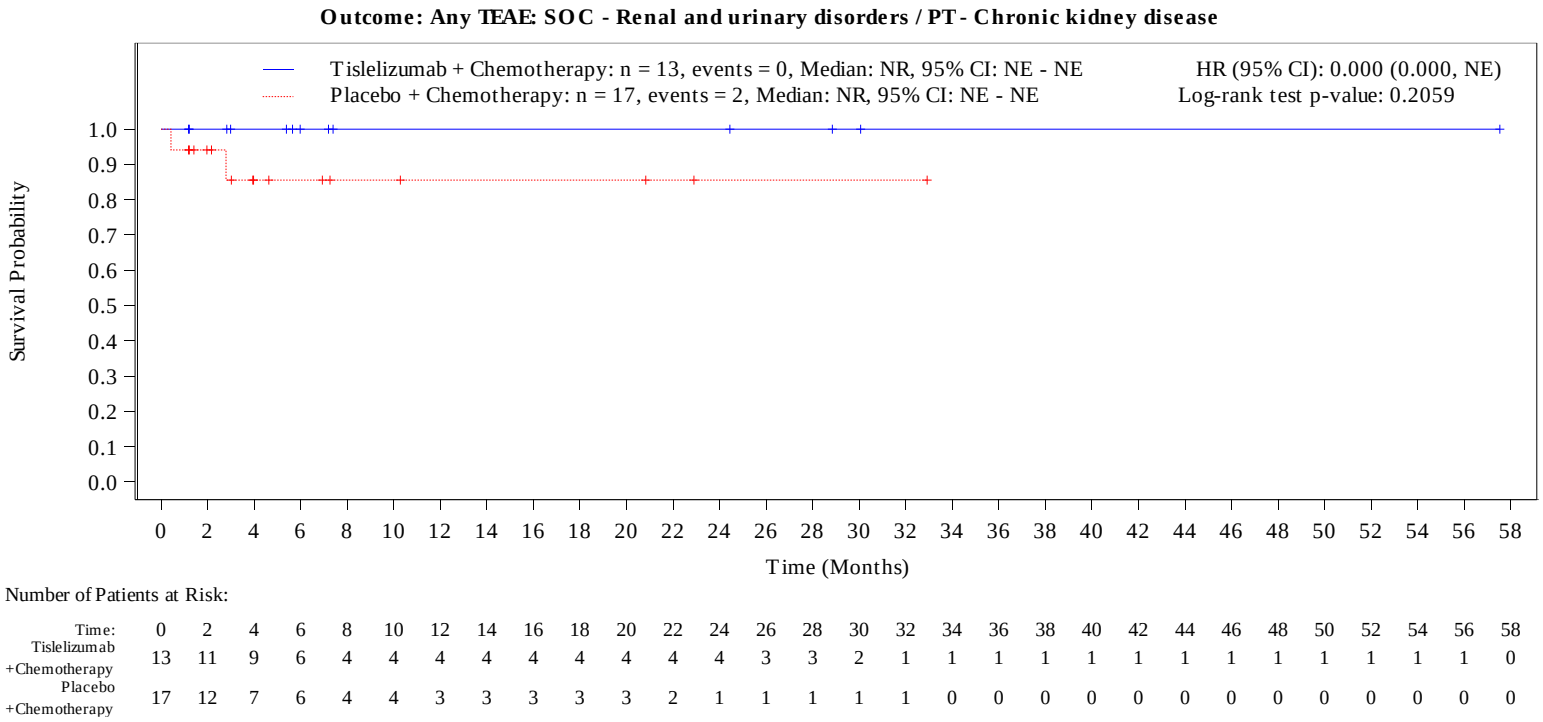
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Placebo +Chemotherapy	17	12	7	6	4	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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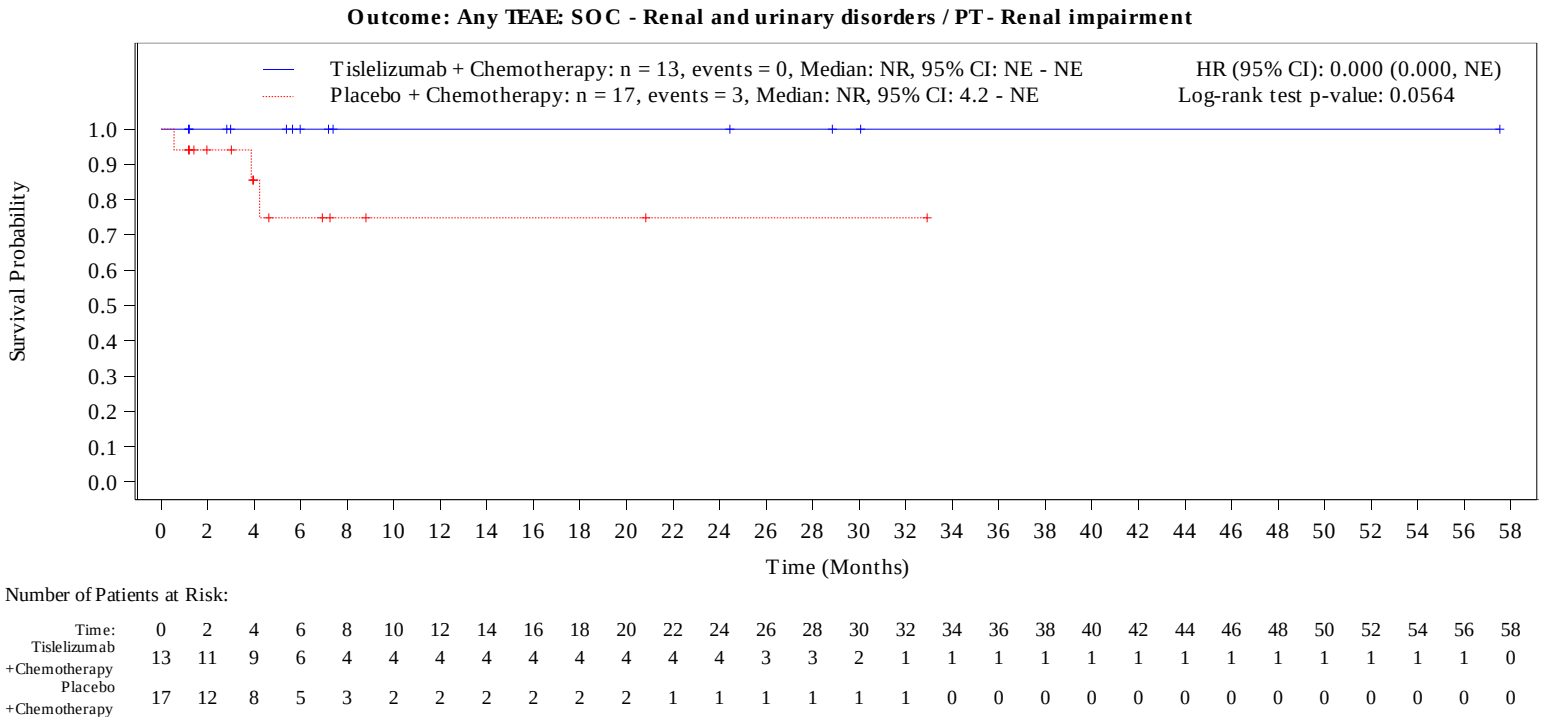
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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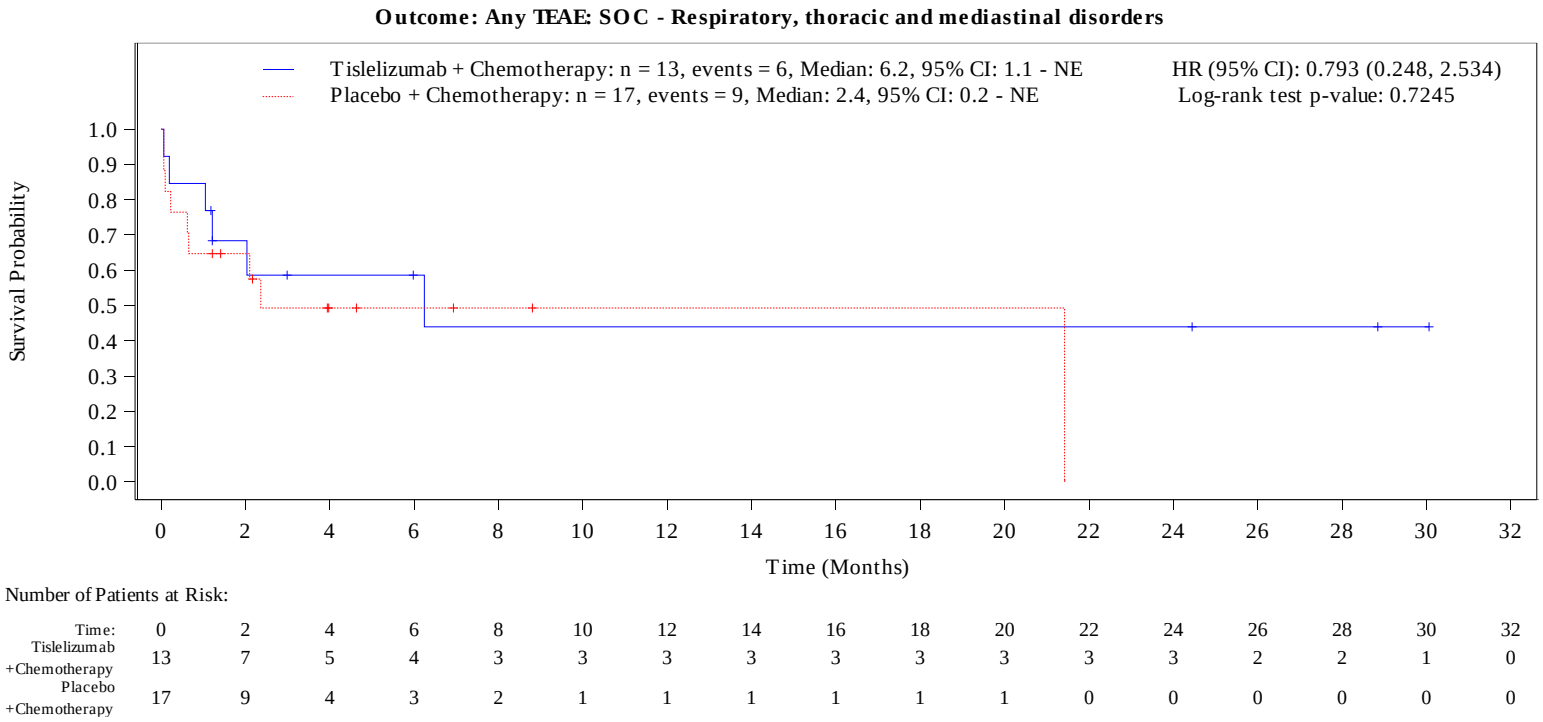

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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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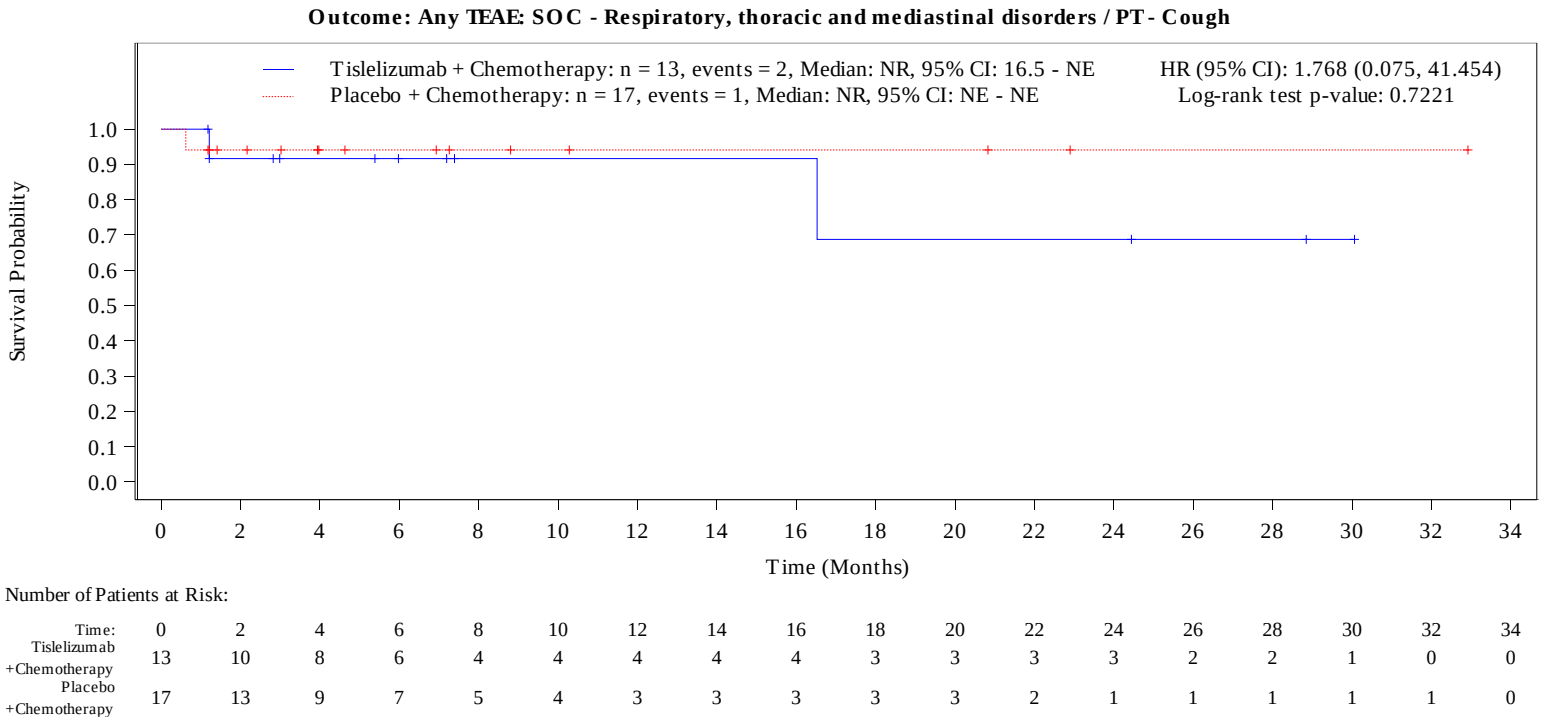

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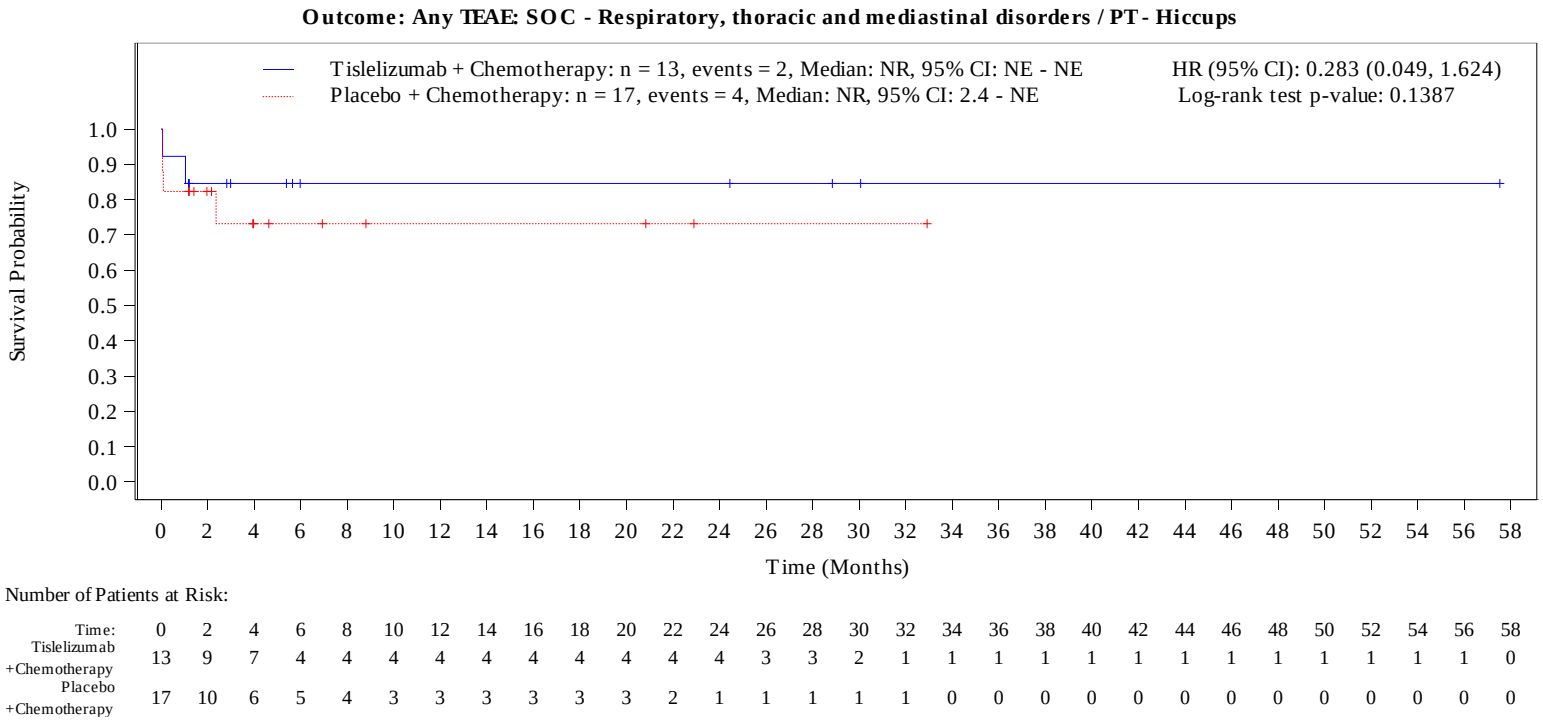

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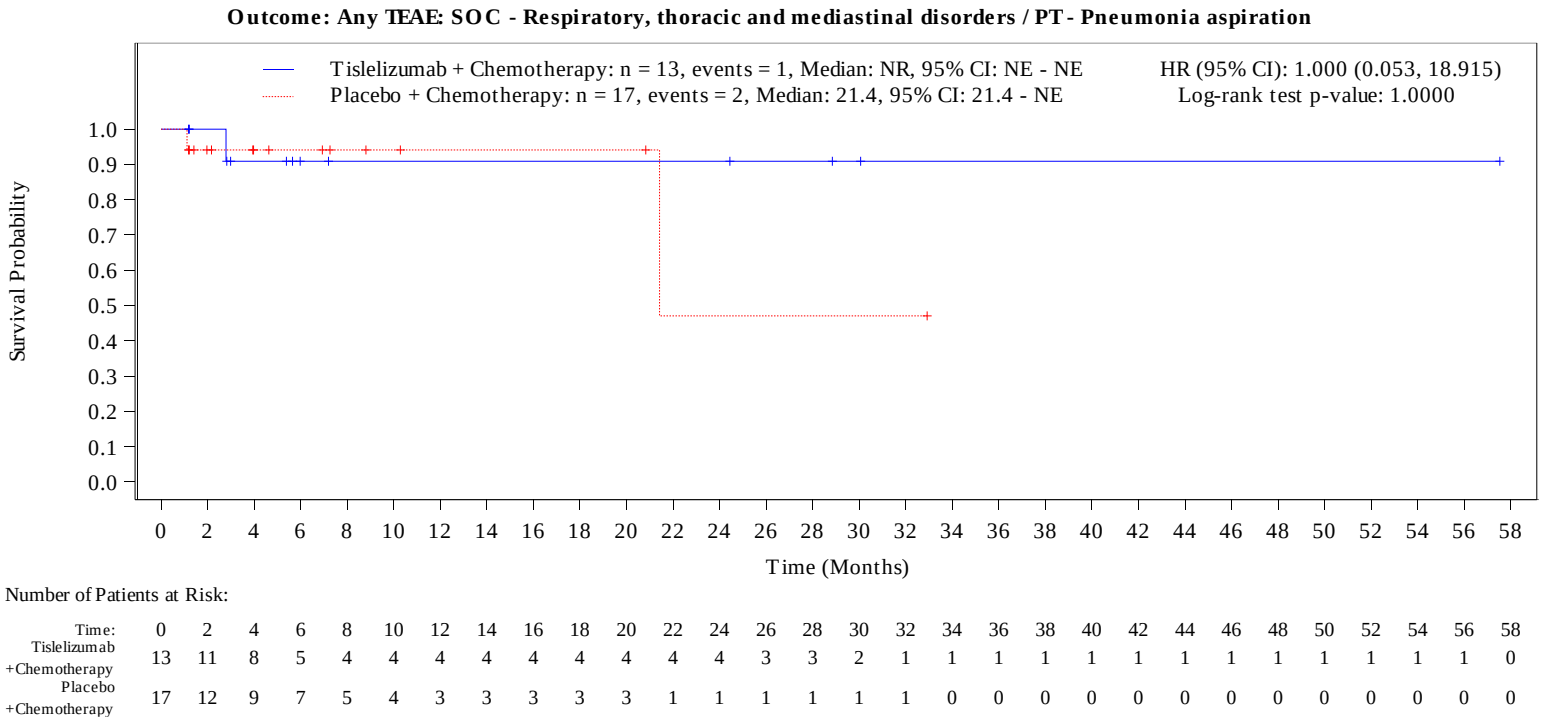

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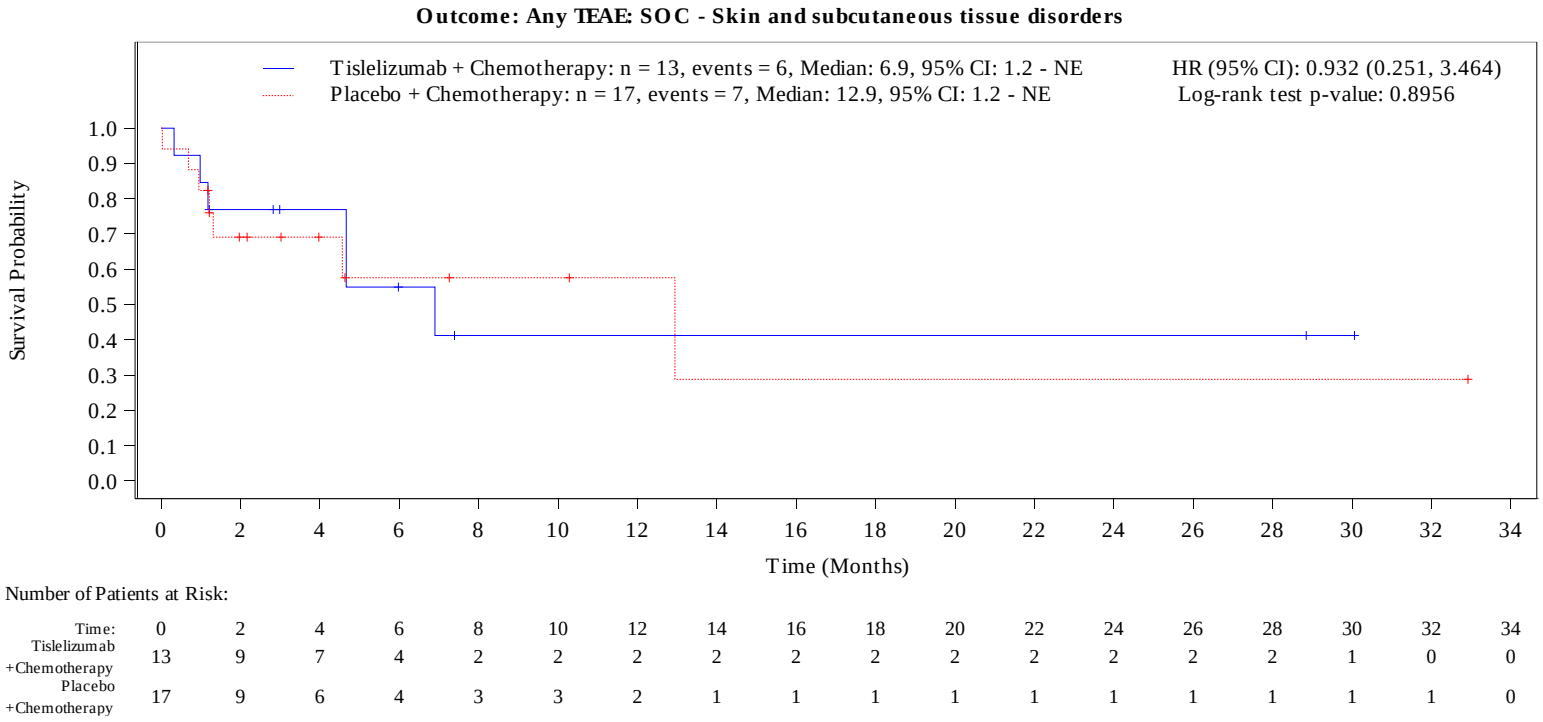

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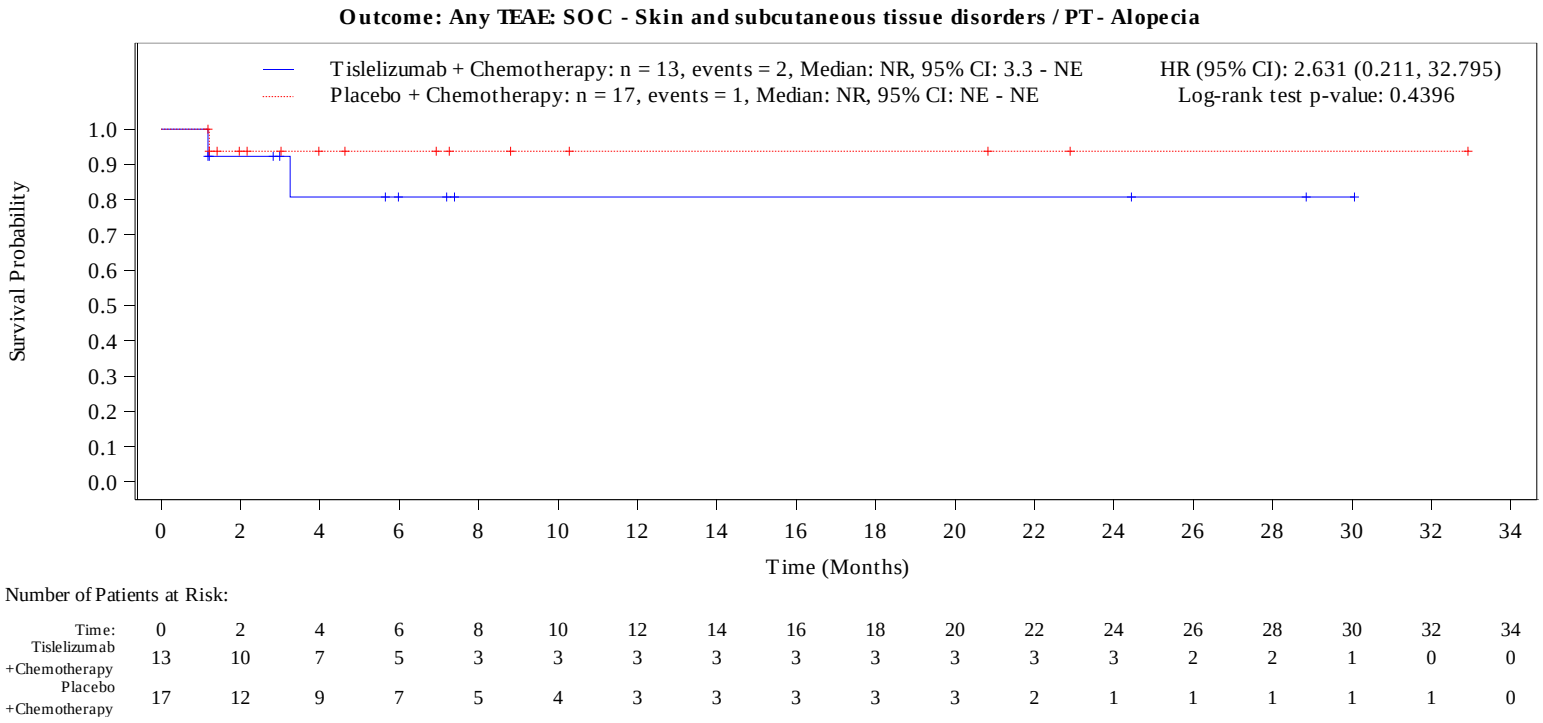

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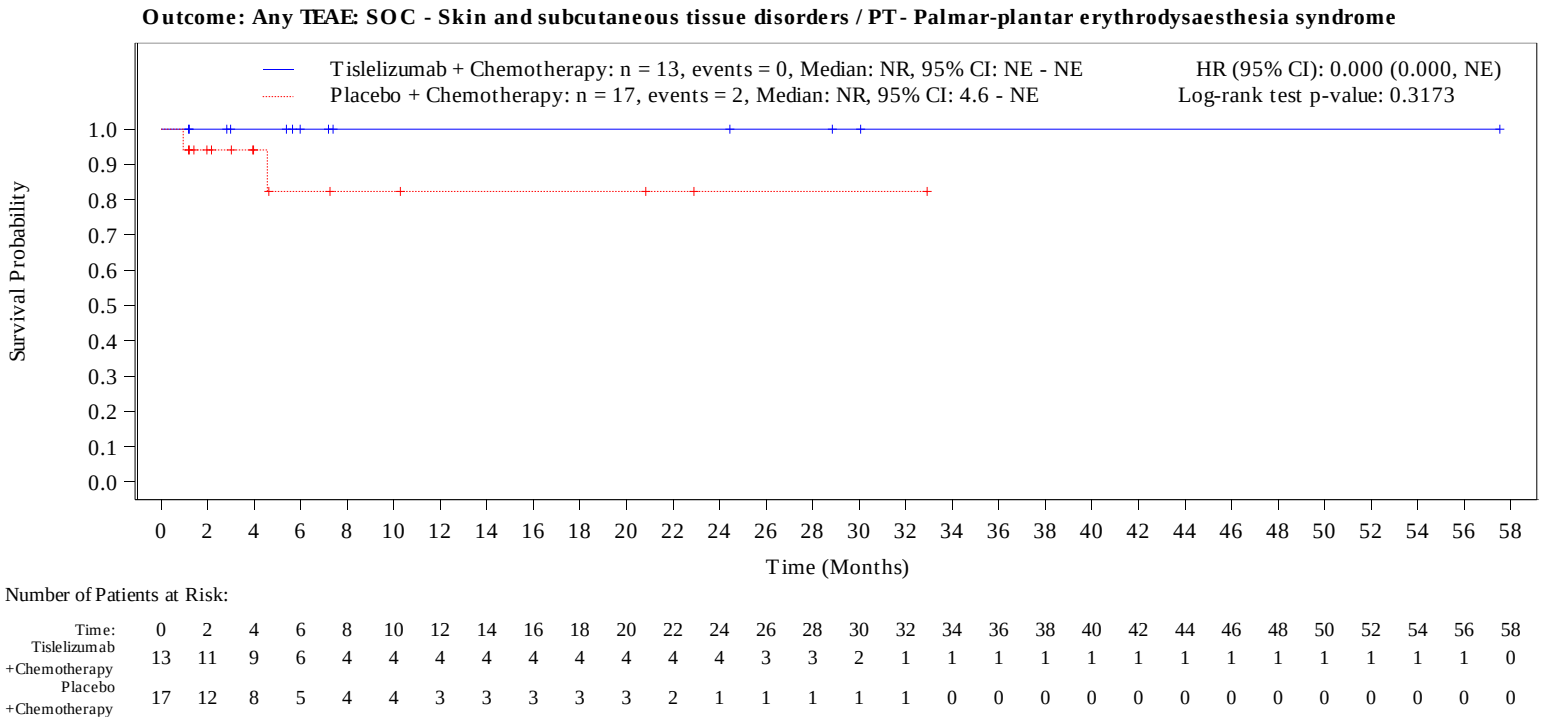

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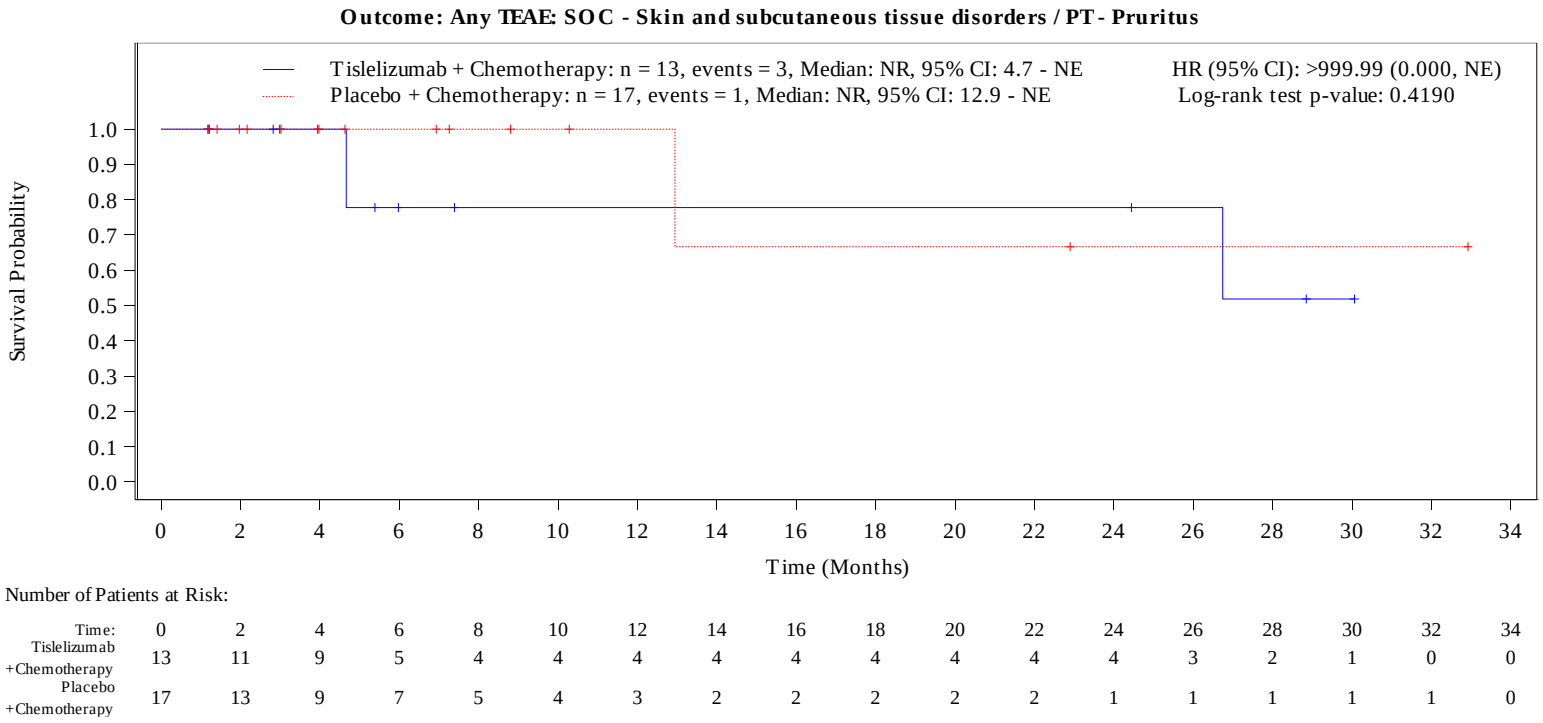
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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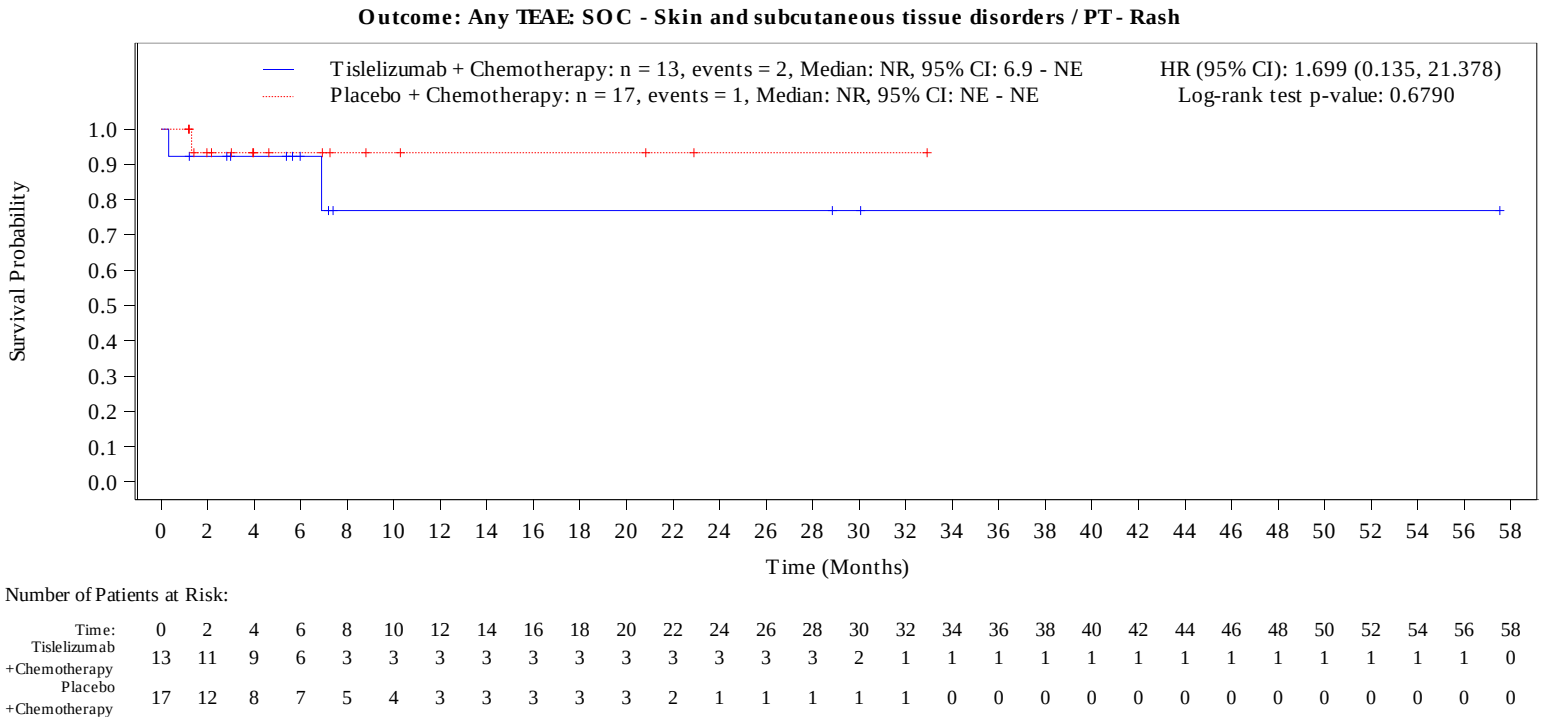

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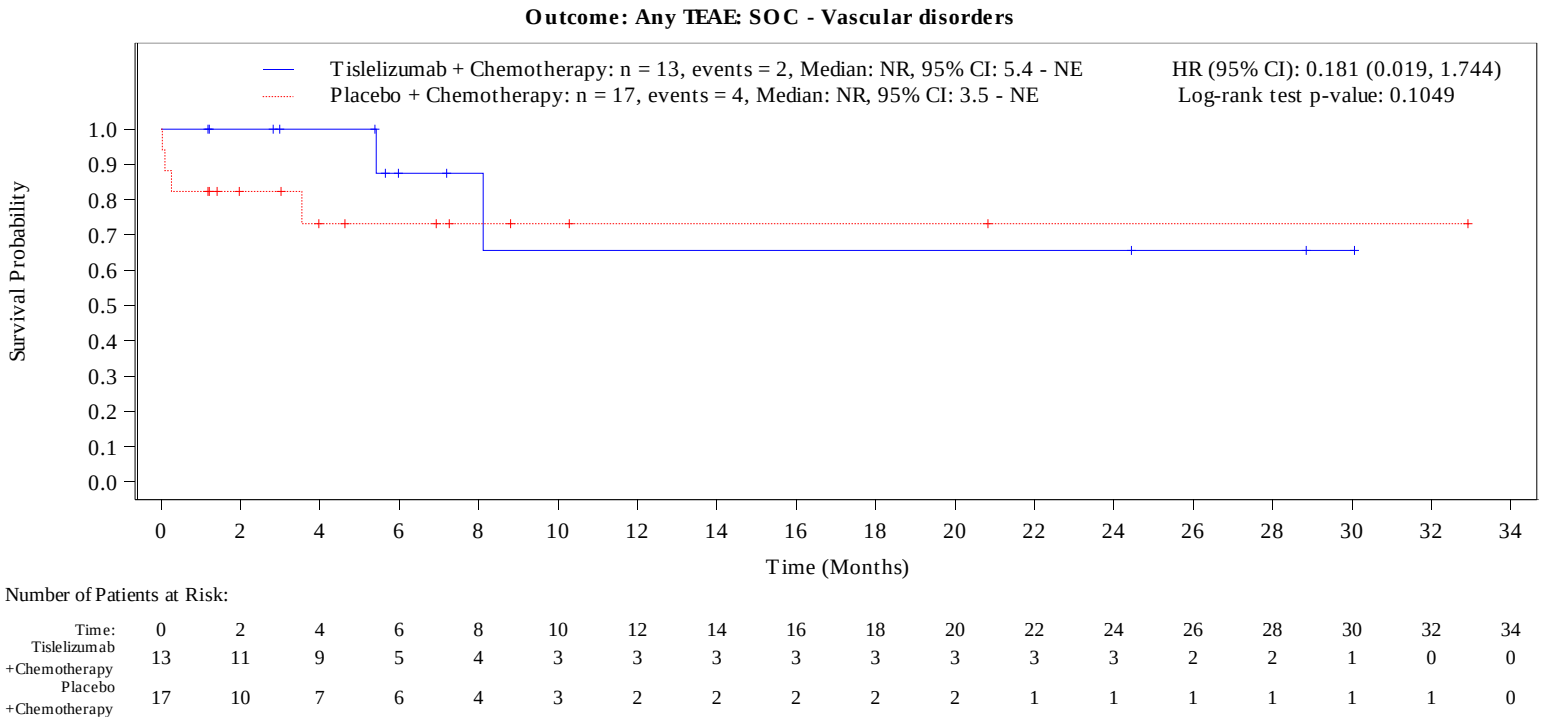

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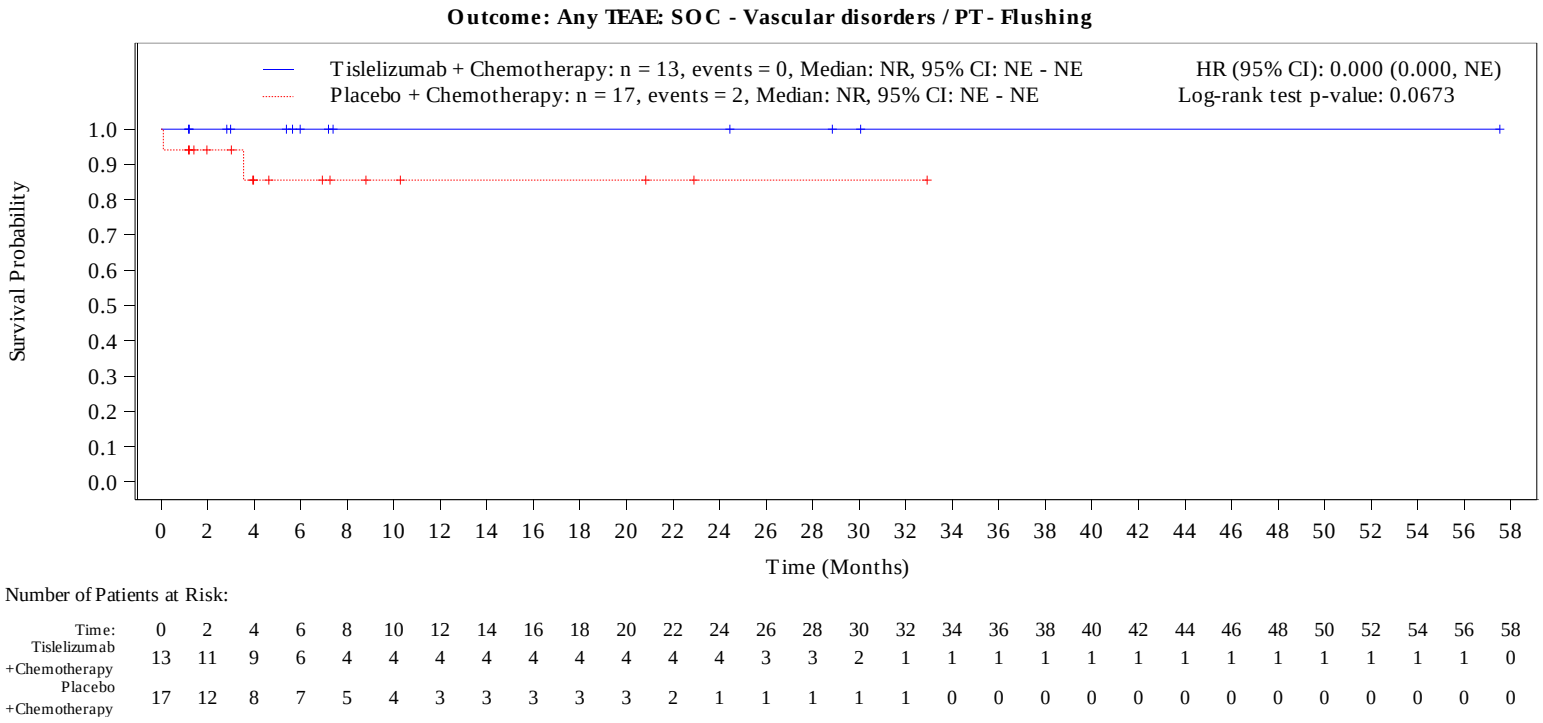

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	8	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

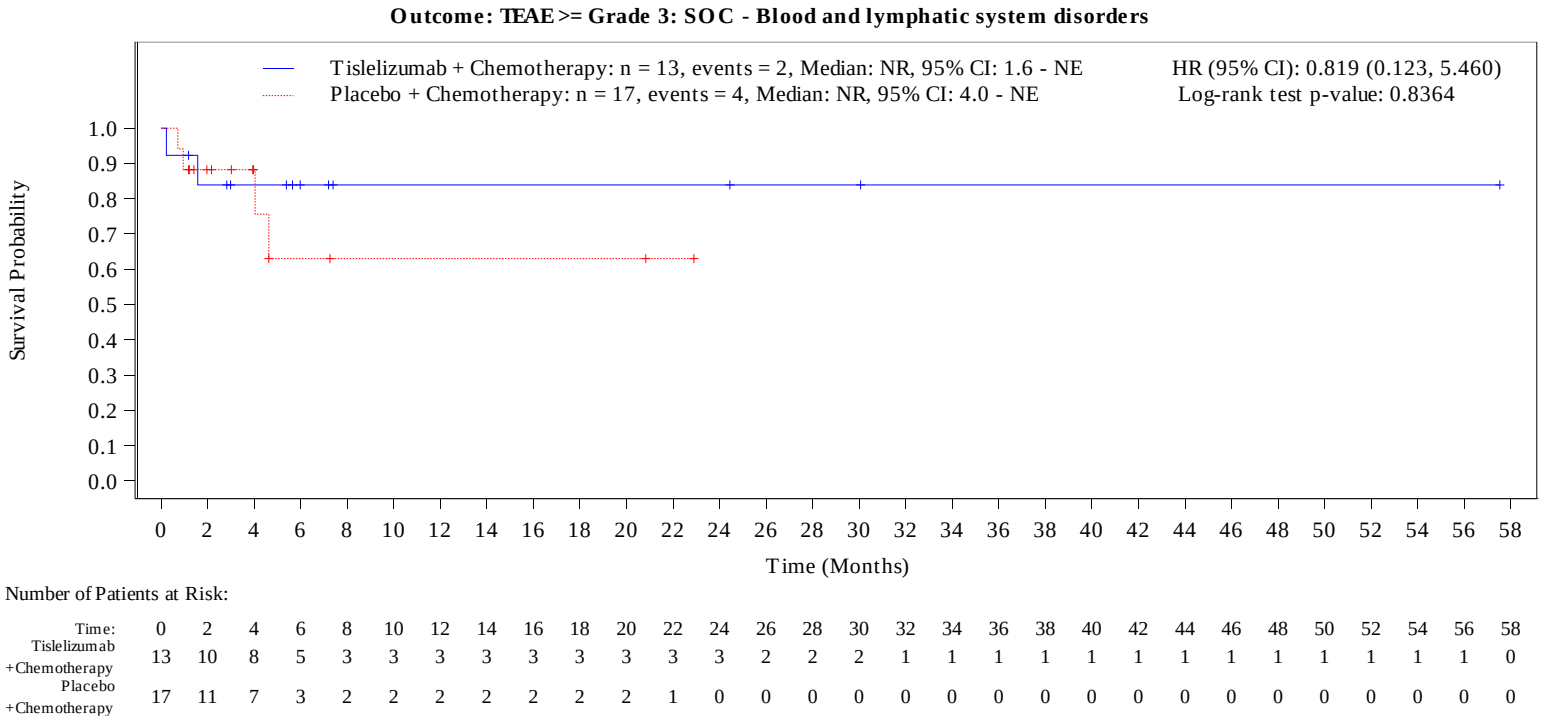

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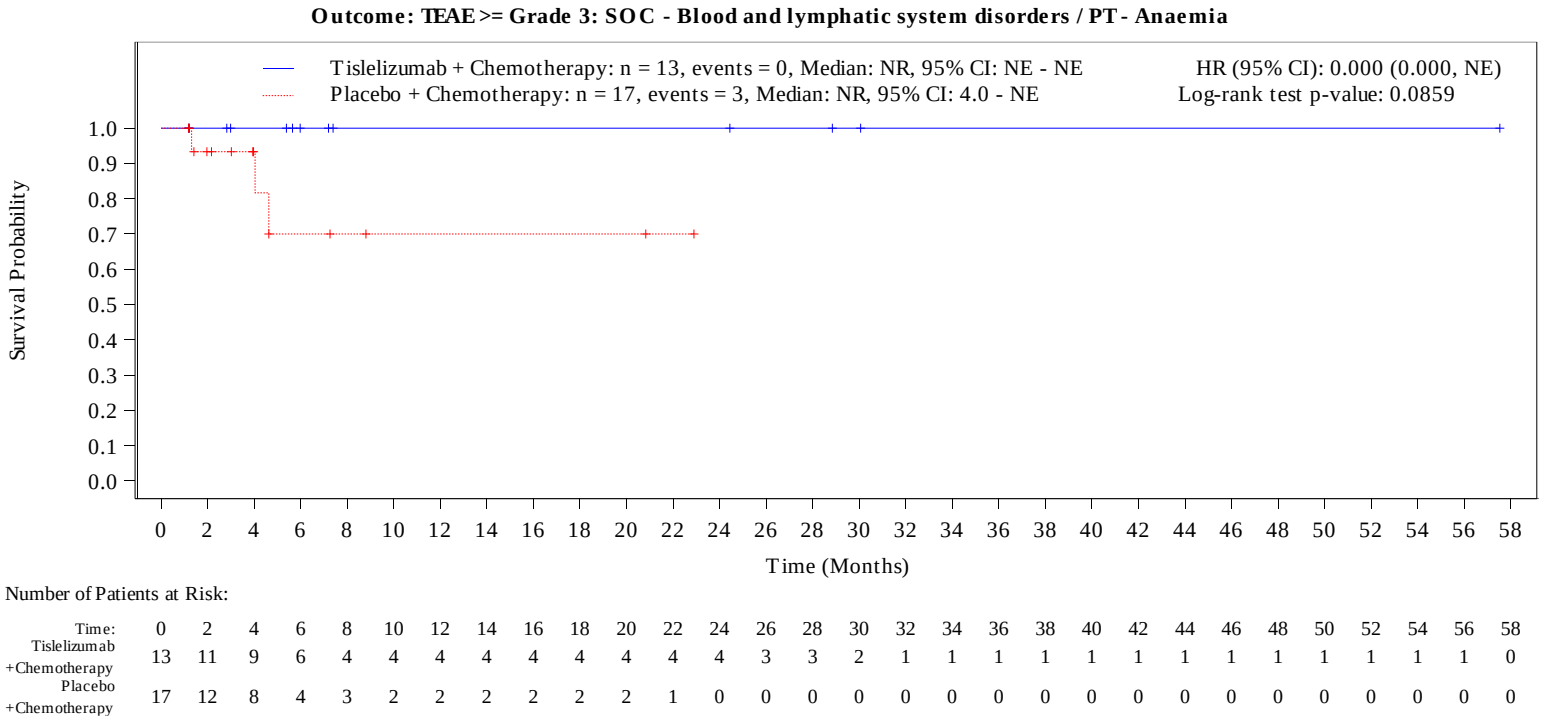
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	8	4	3	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

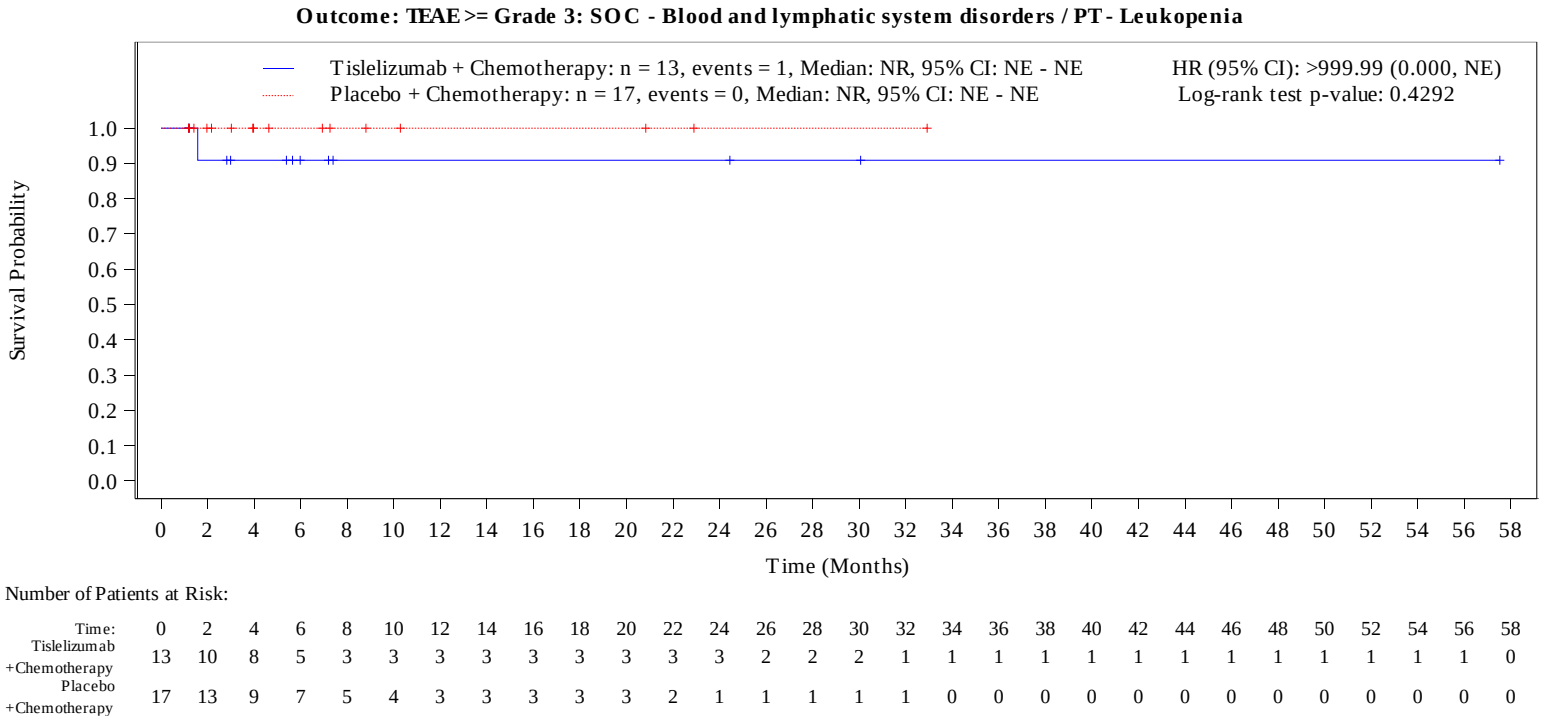

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
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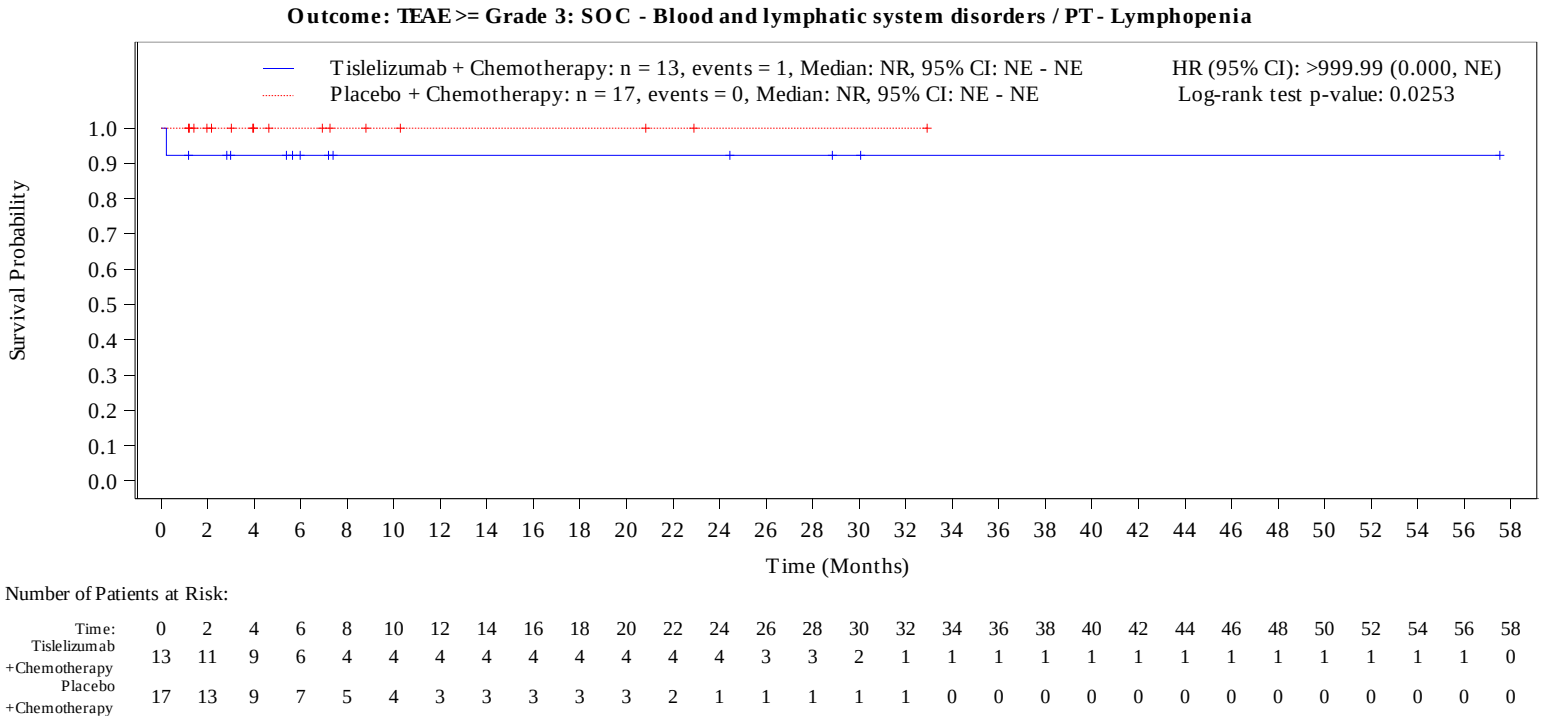

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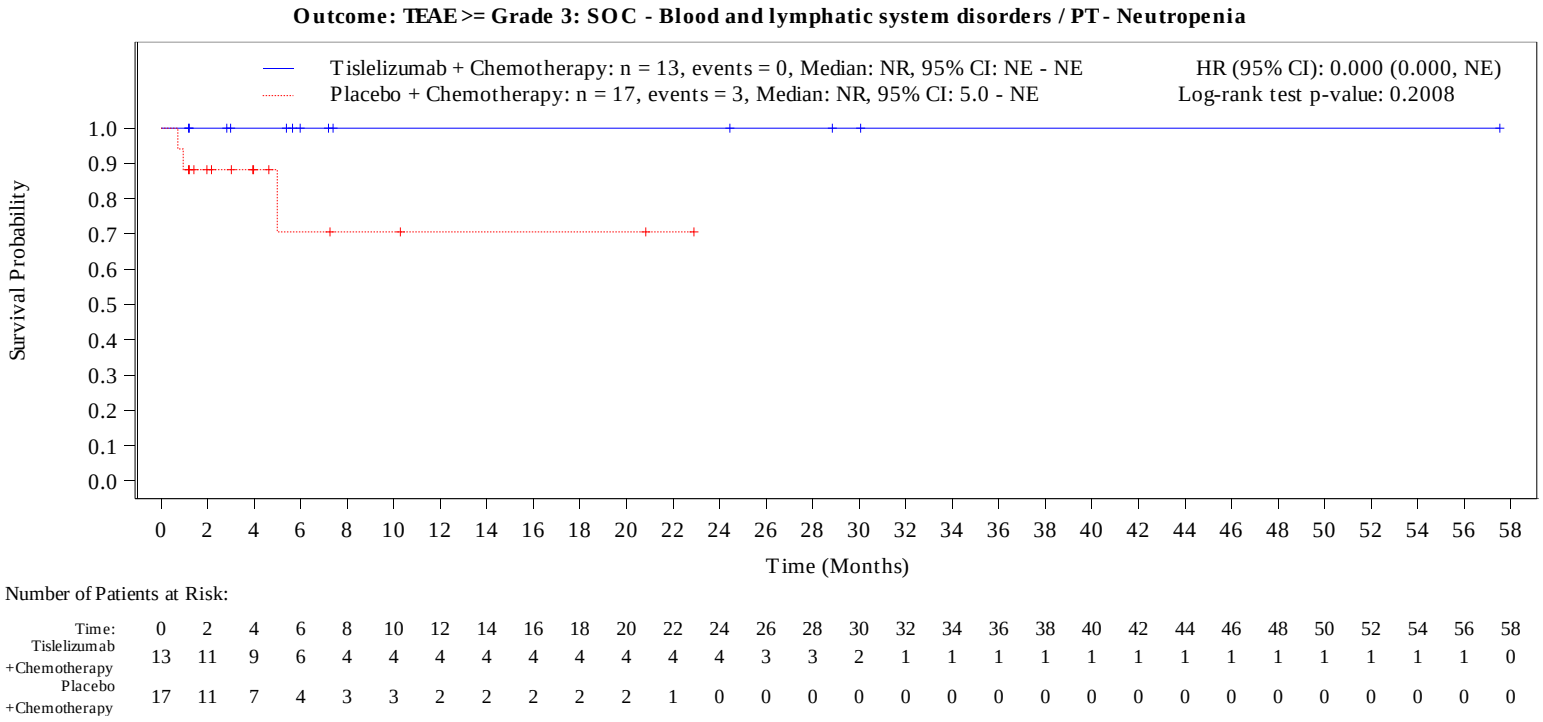

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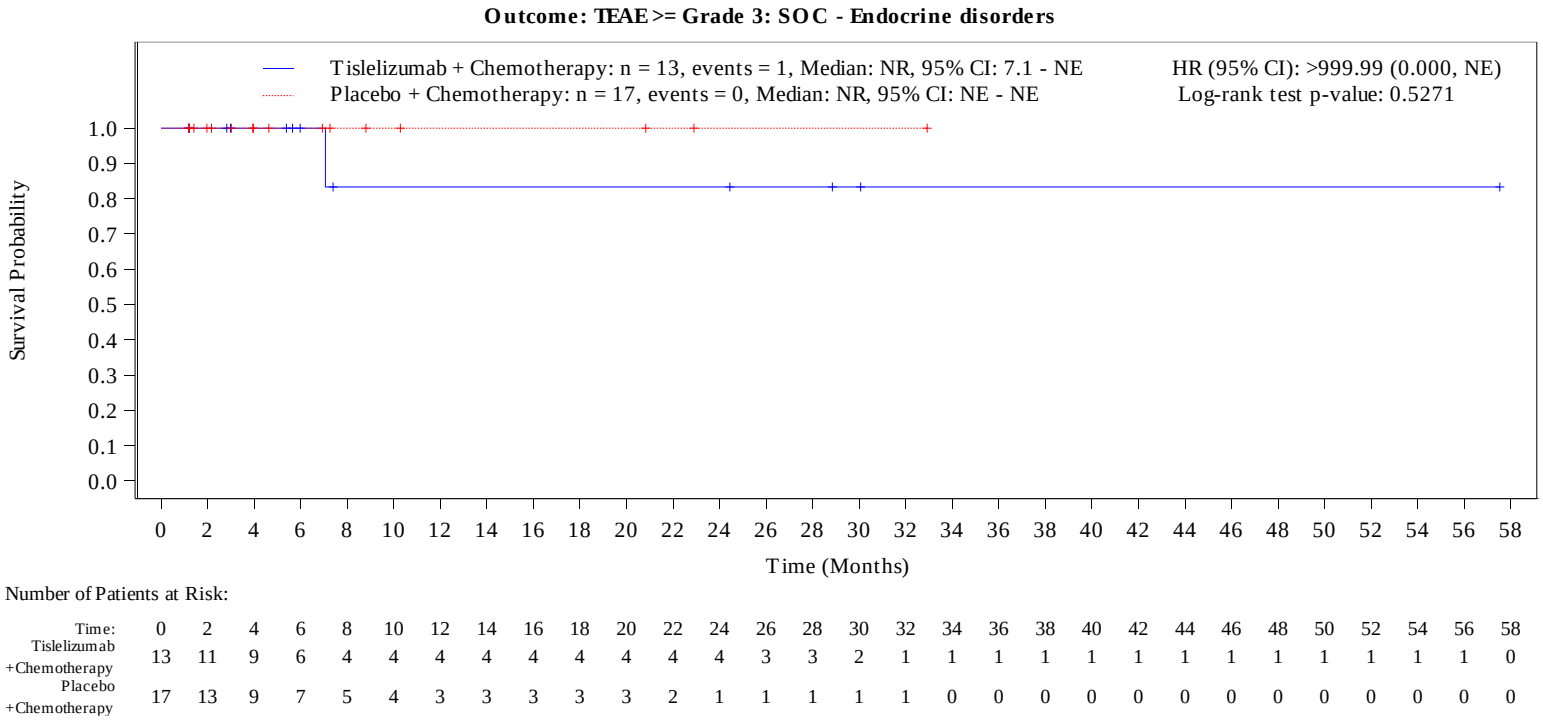

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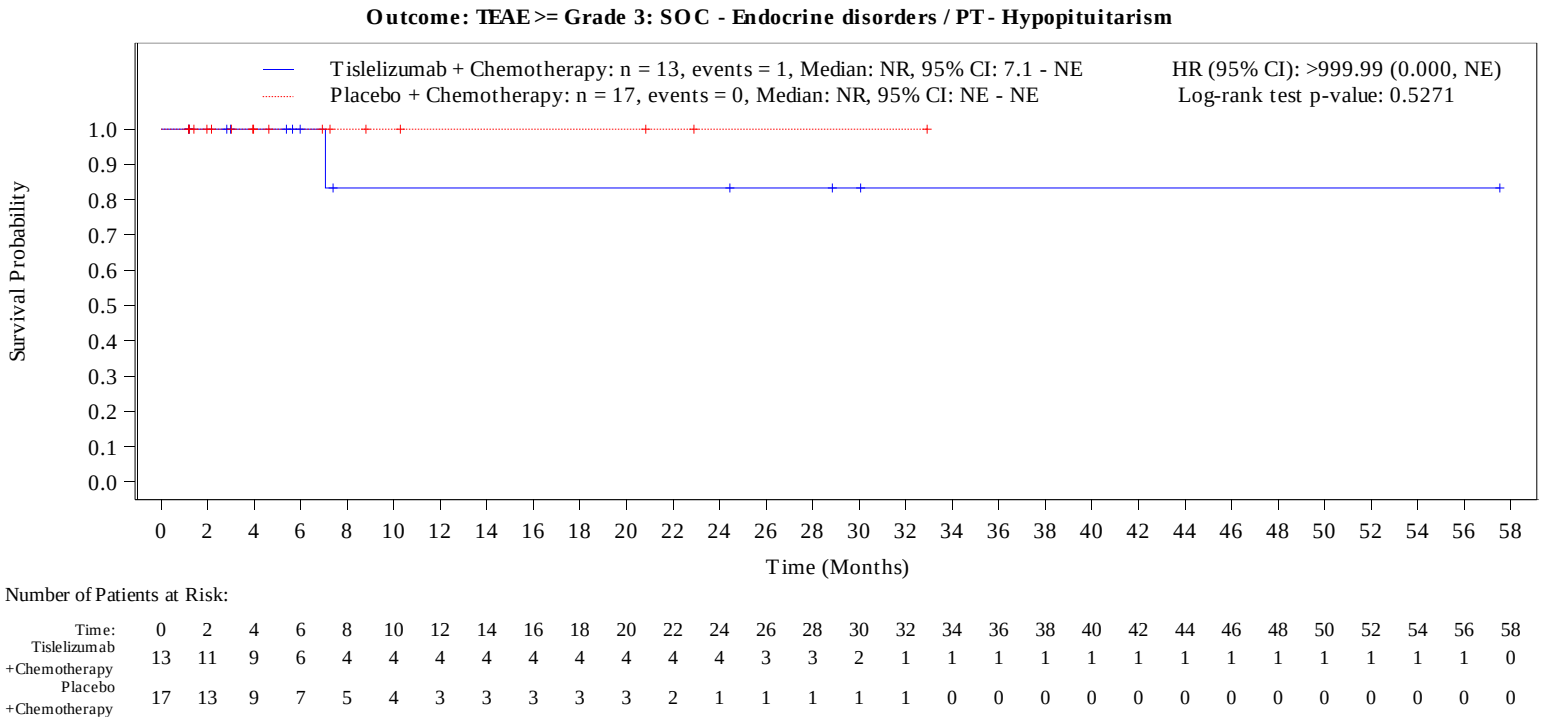

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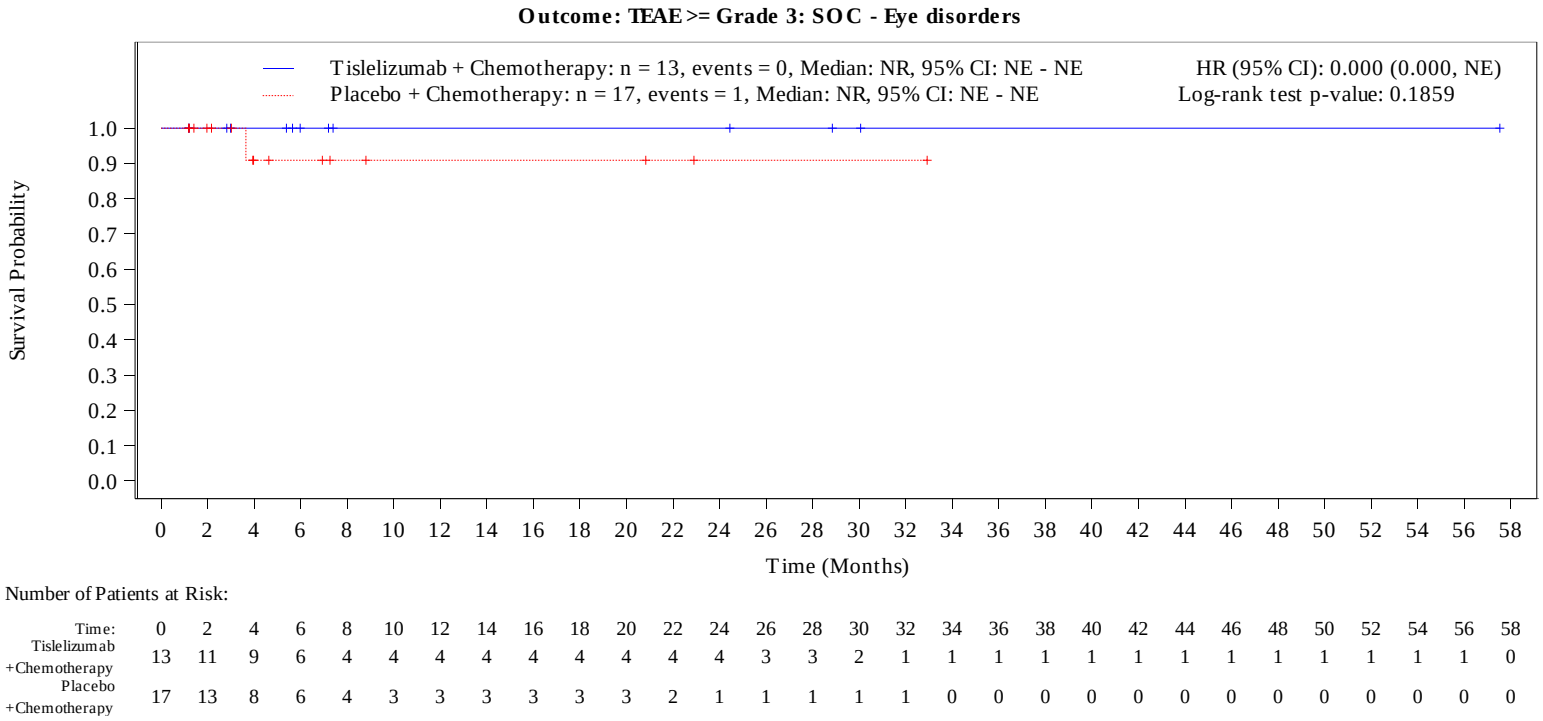

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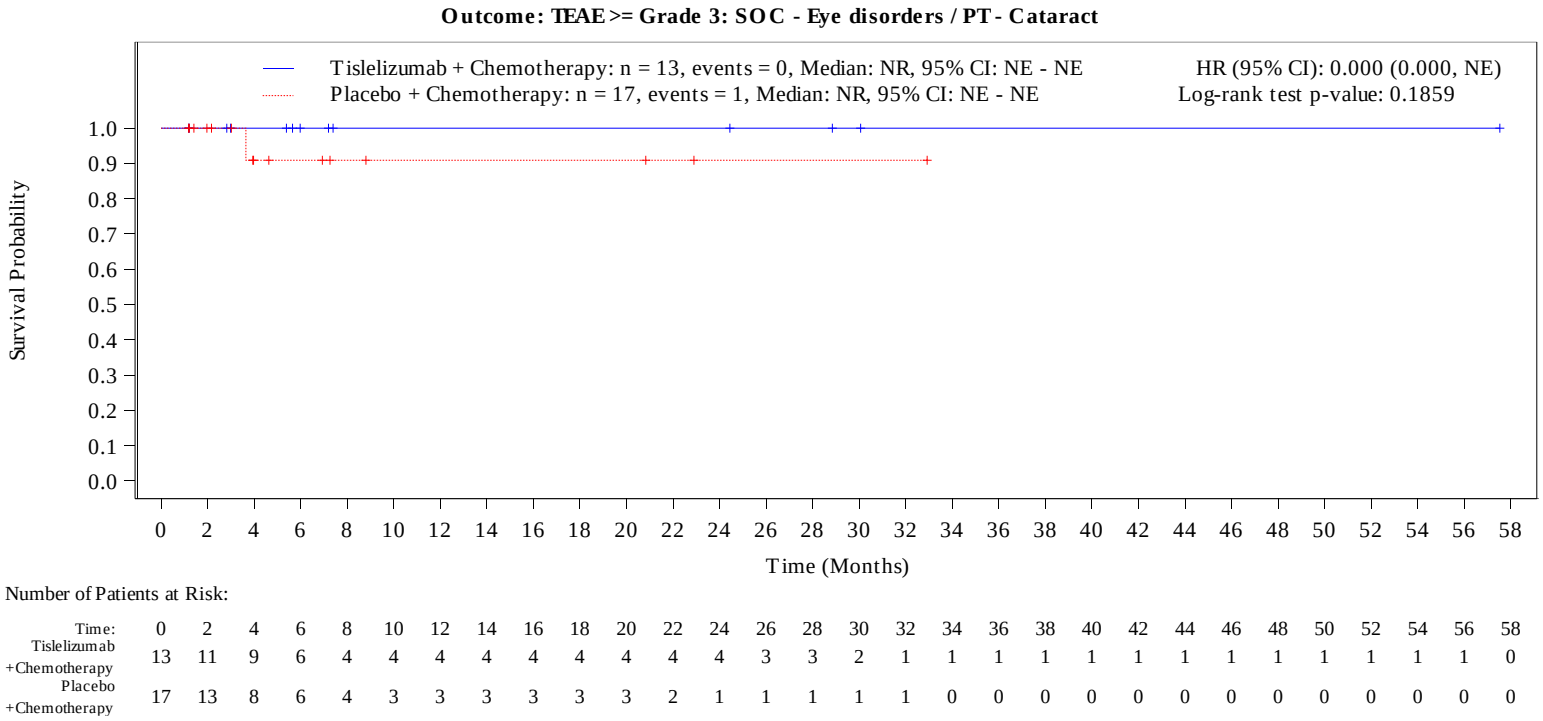

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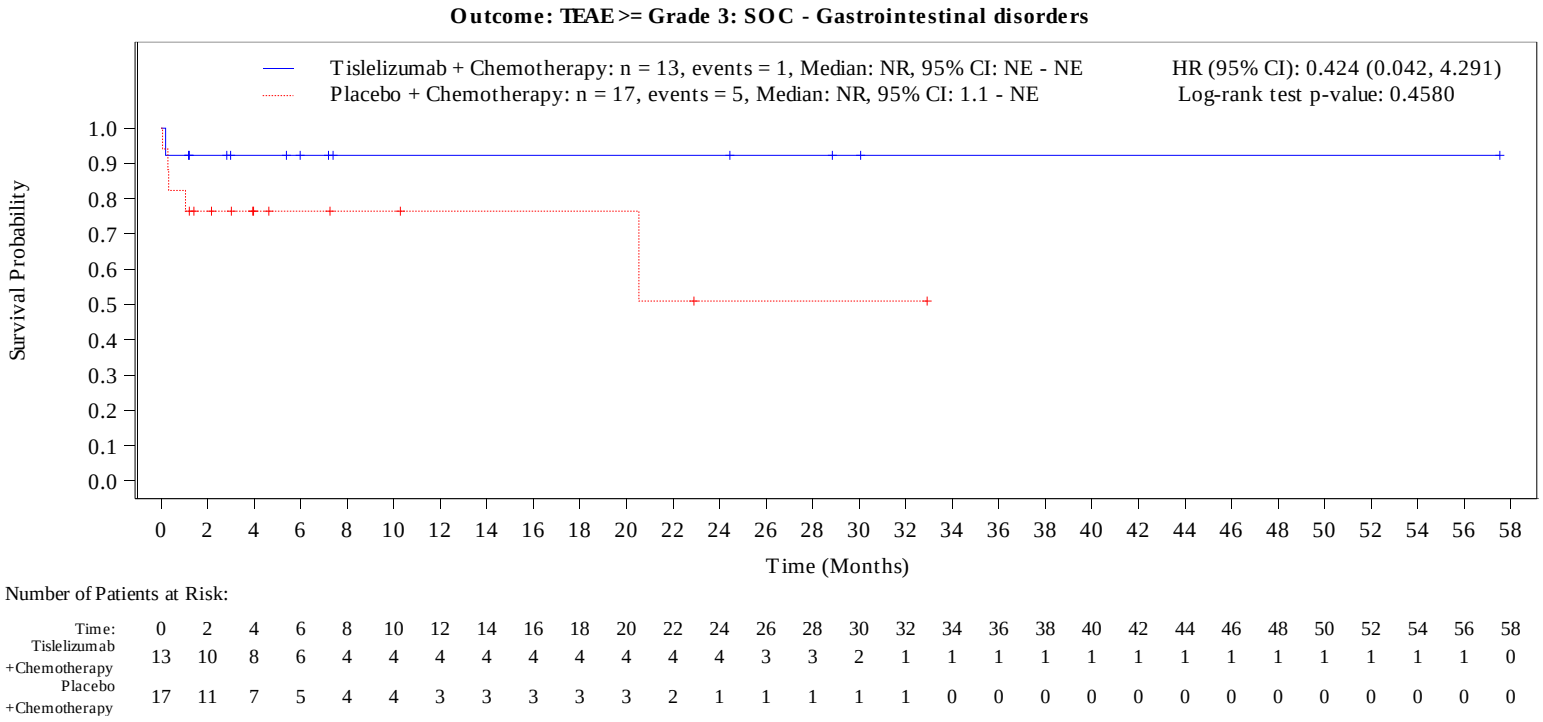

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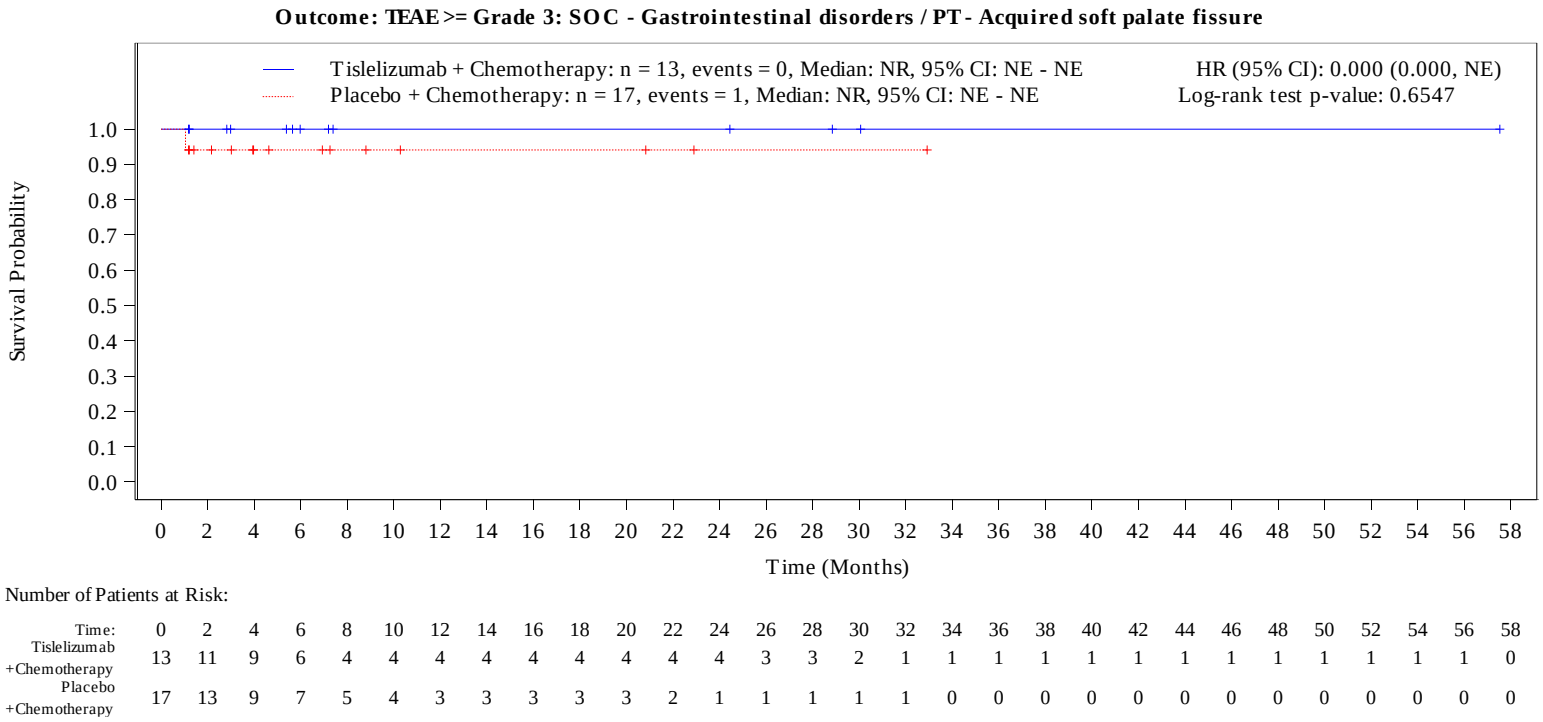

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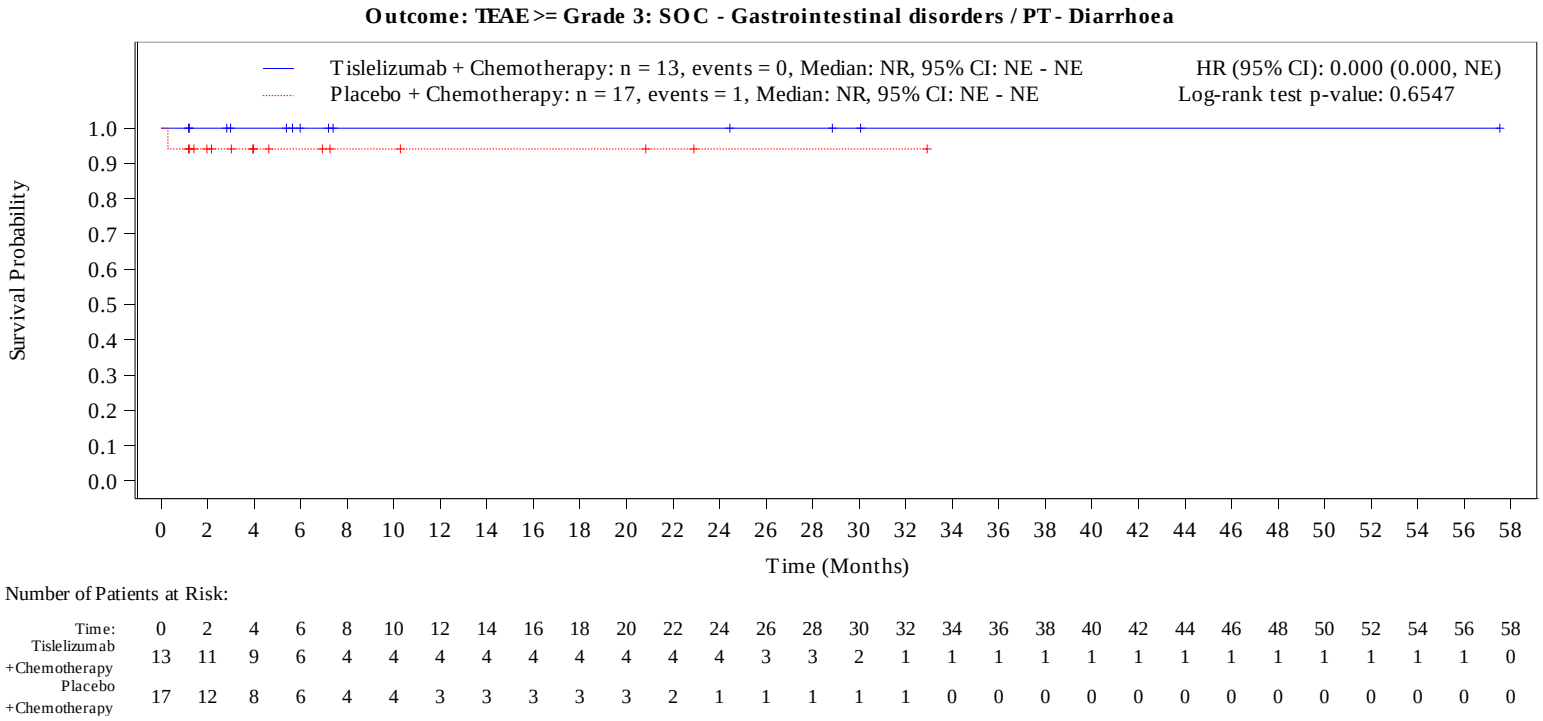

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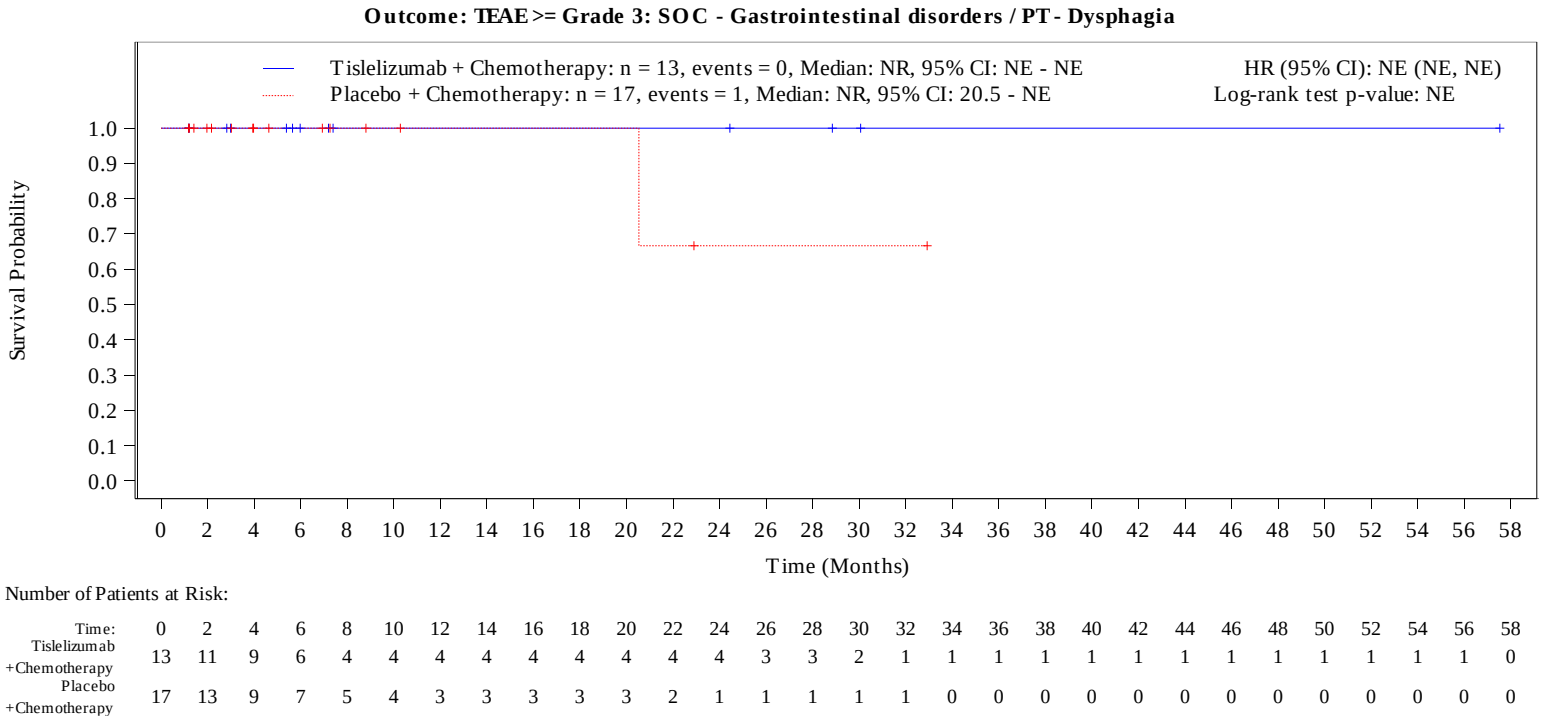

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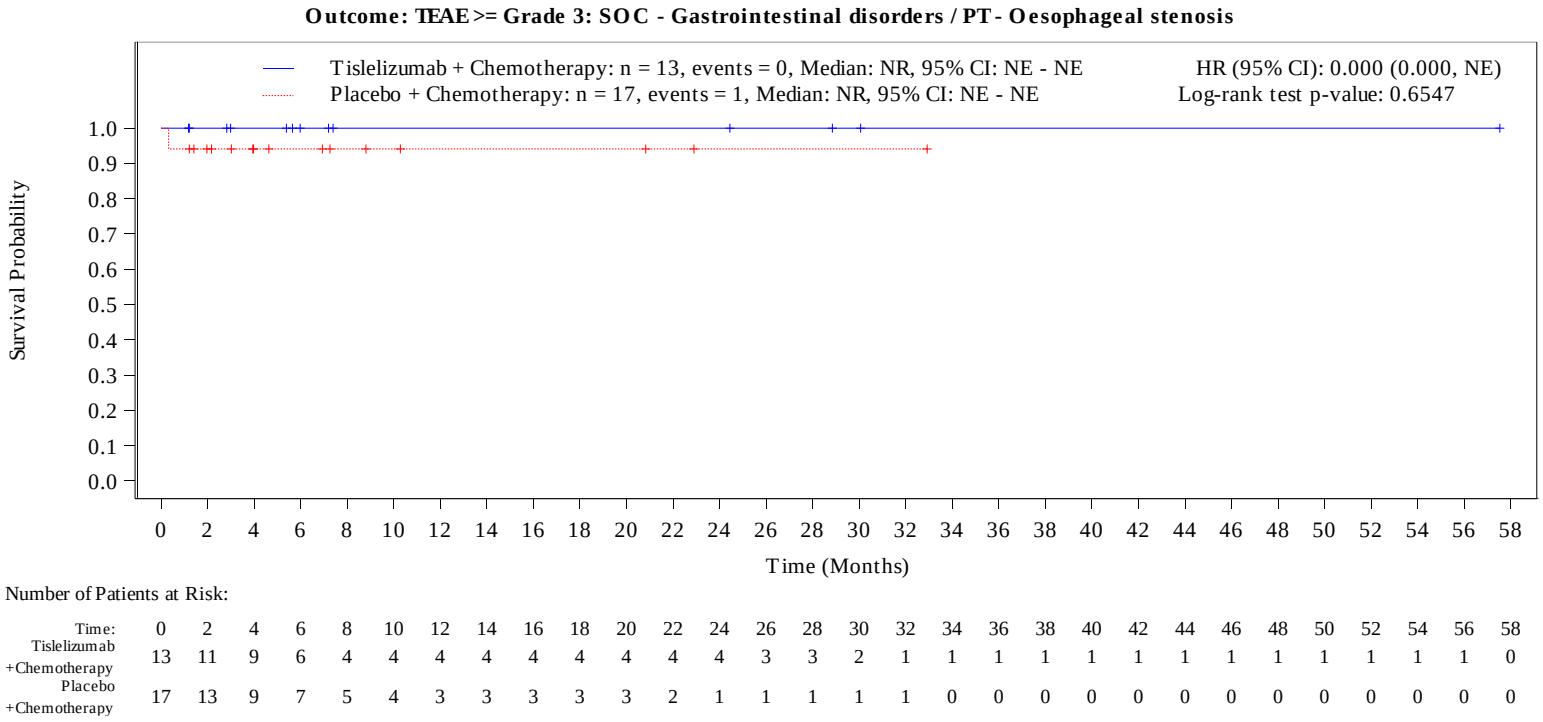

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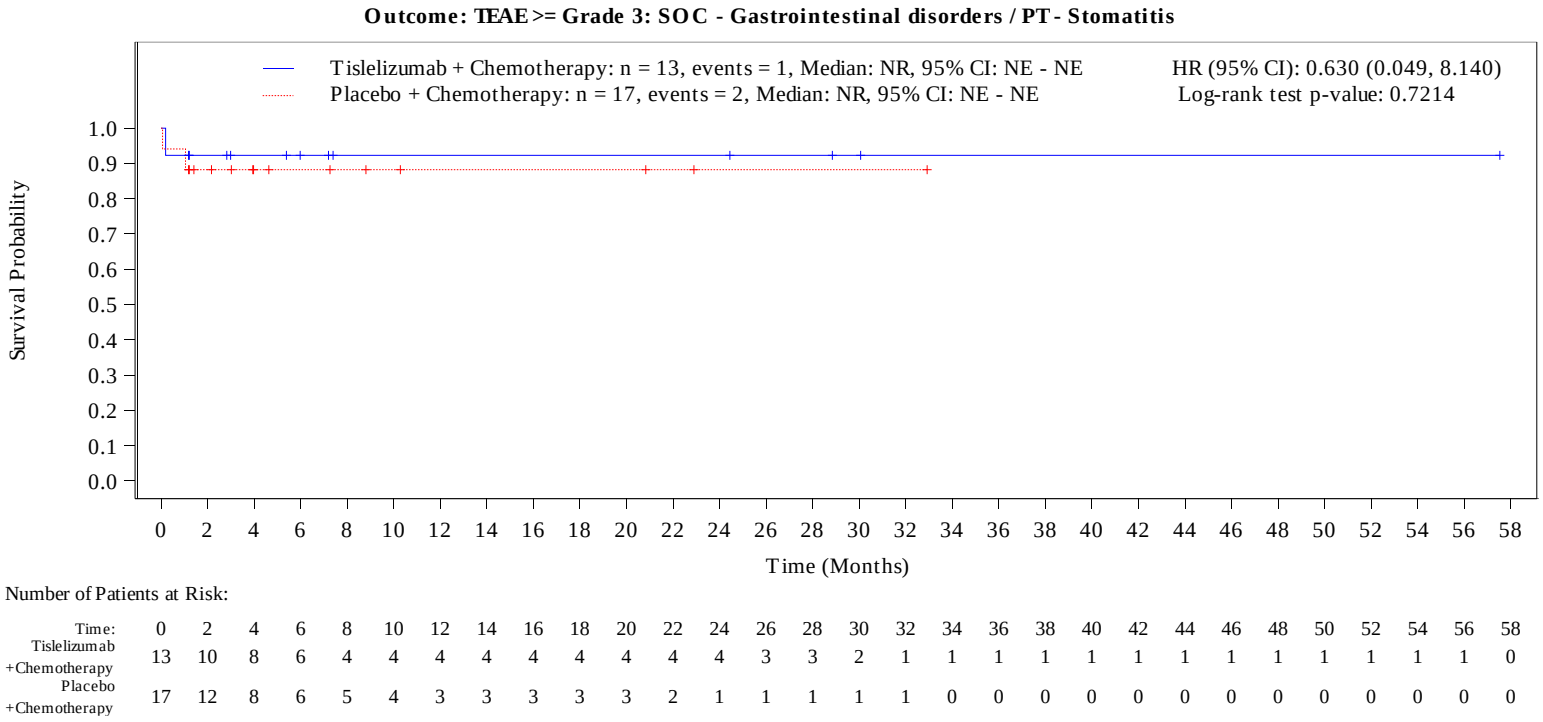
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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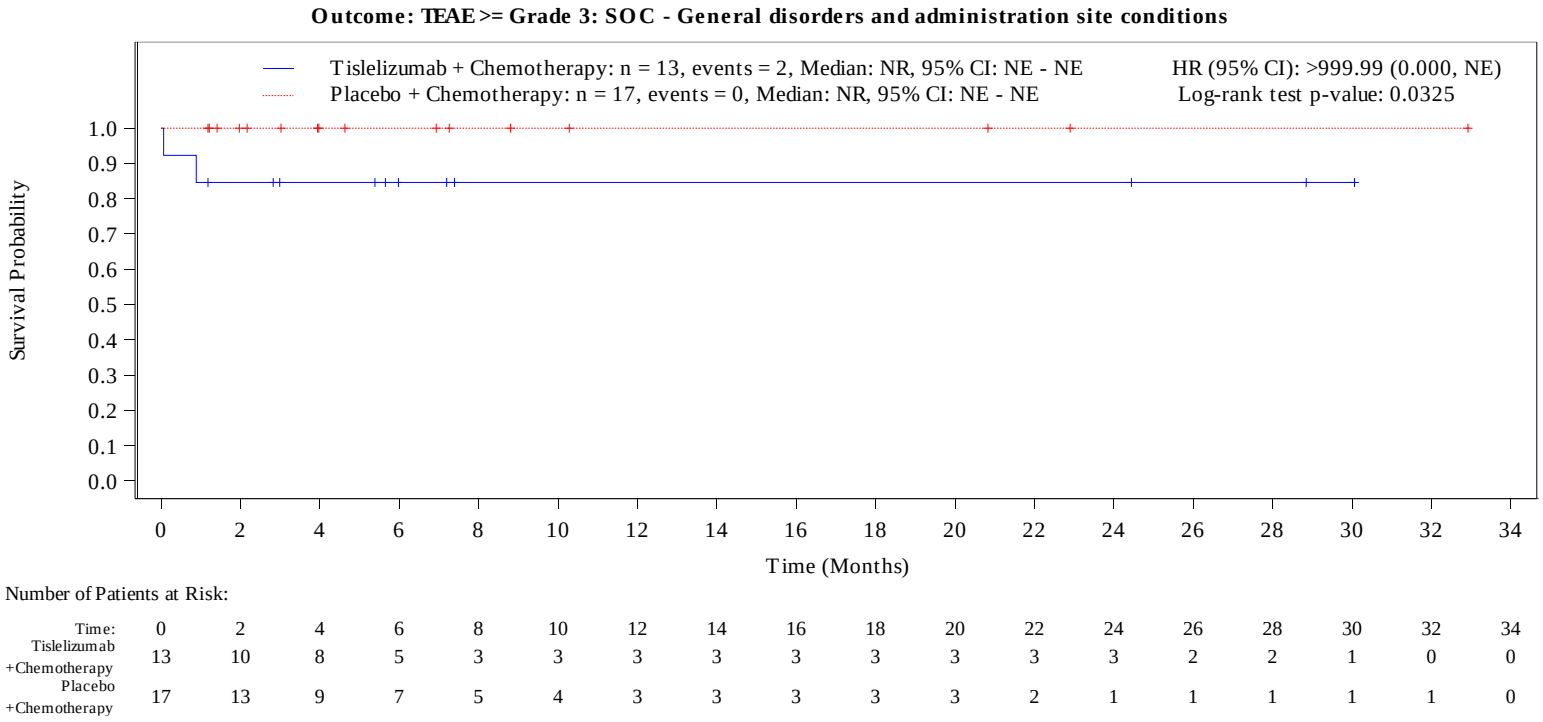

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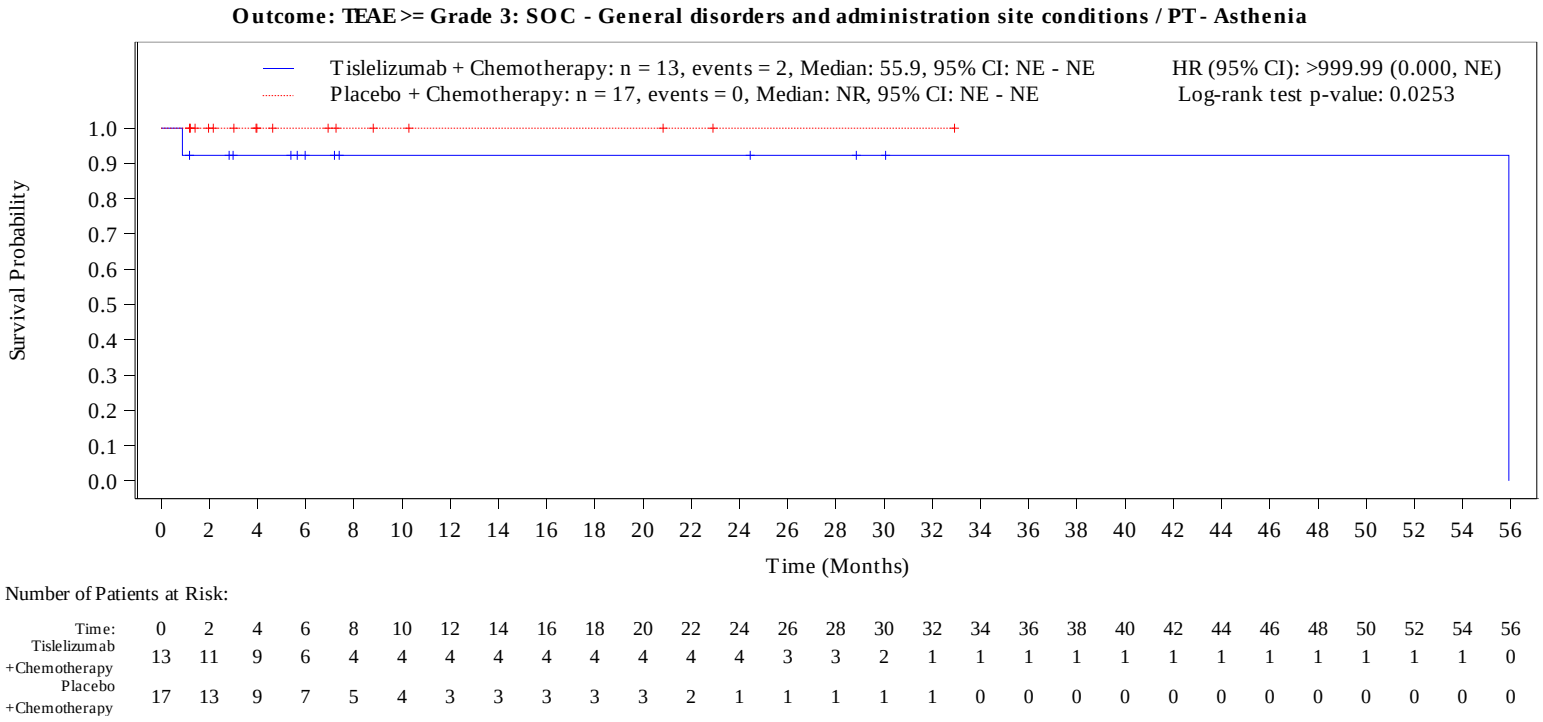

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Figure 14.3.1.3:
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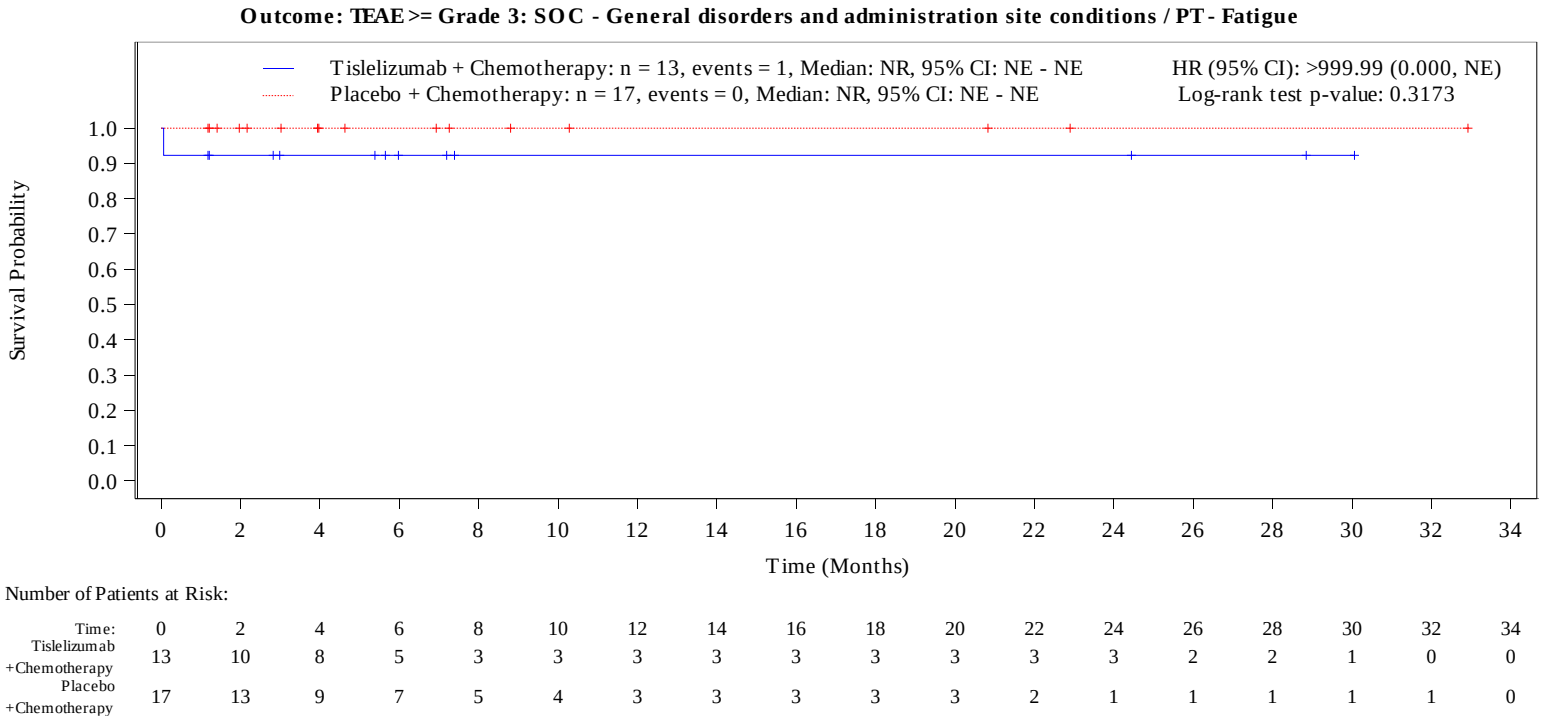

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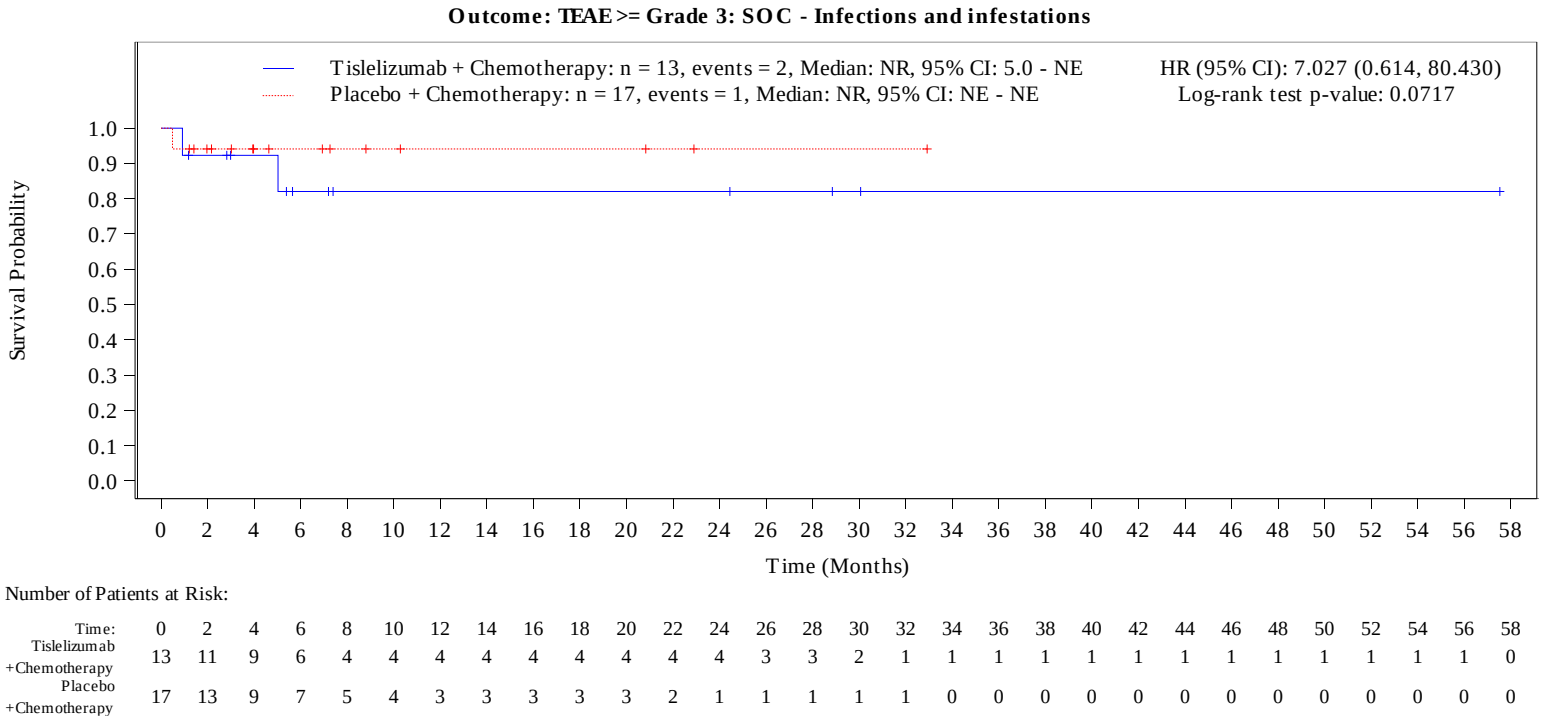

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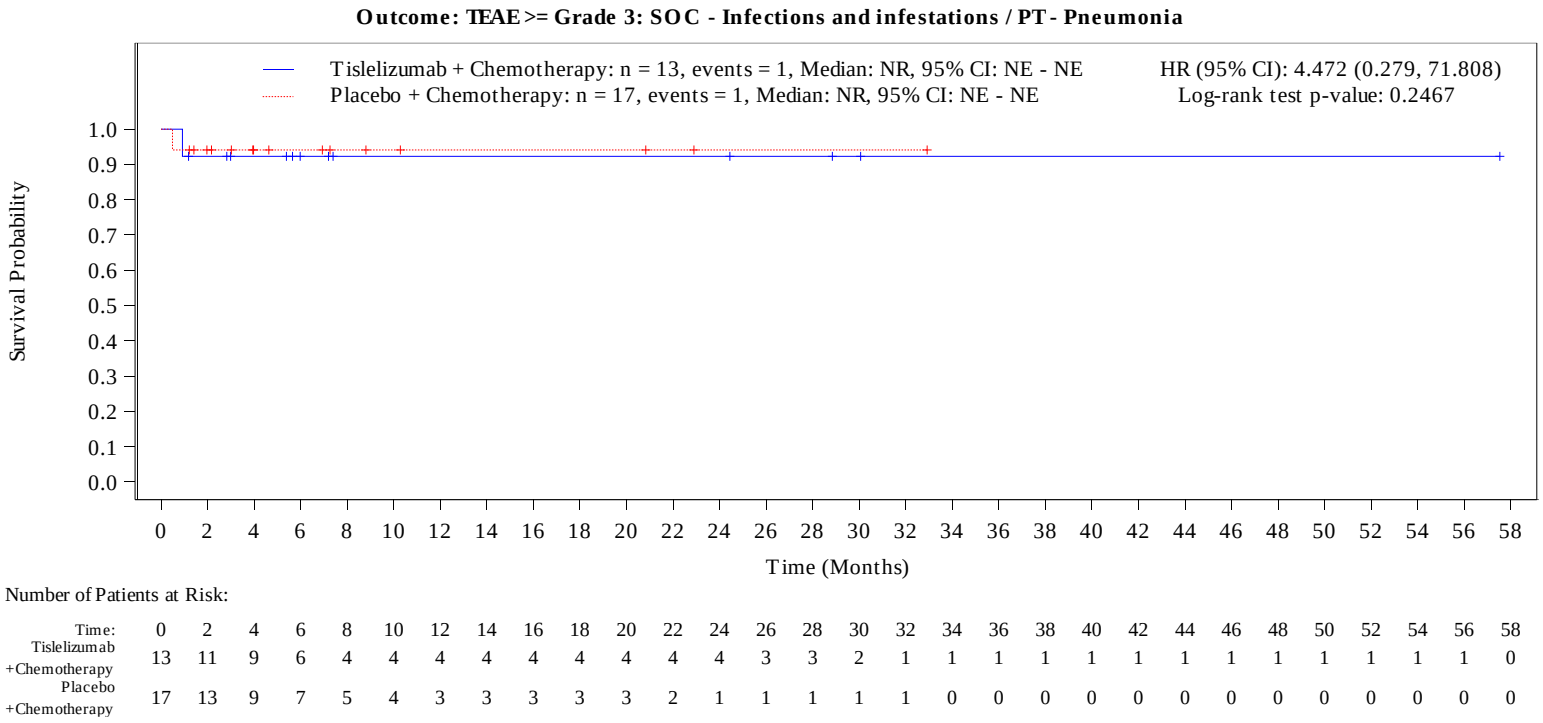

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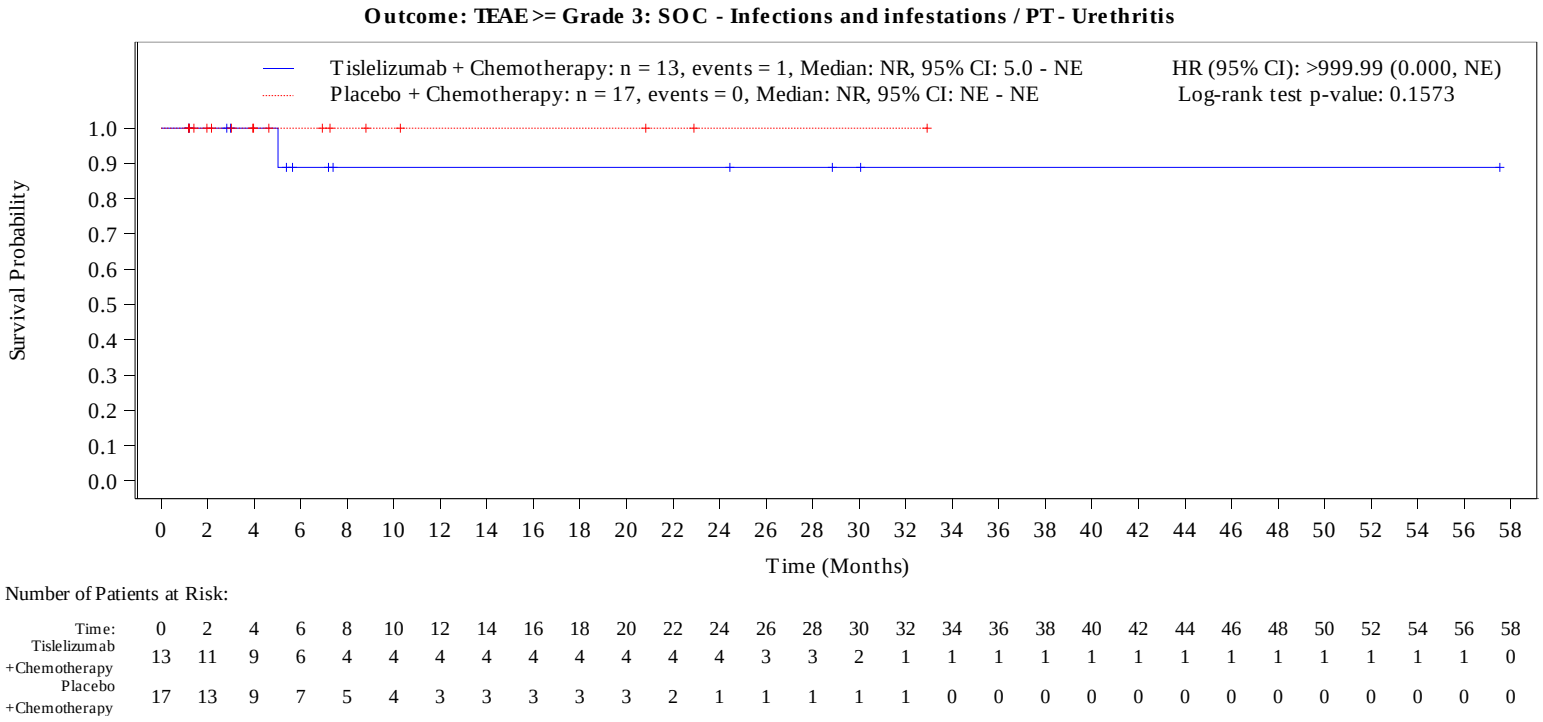

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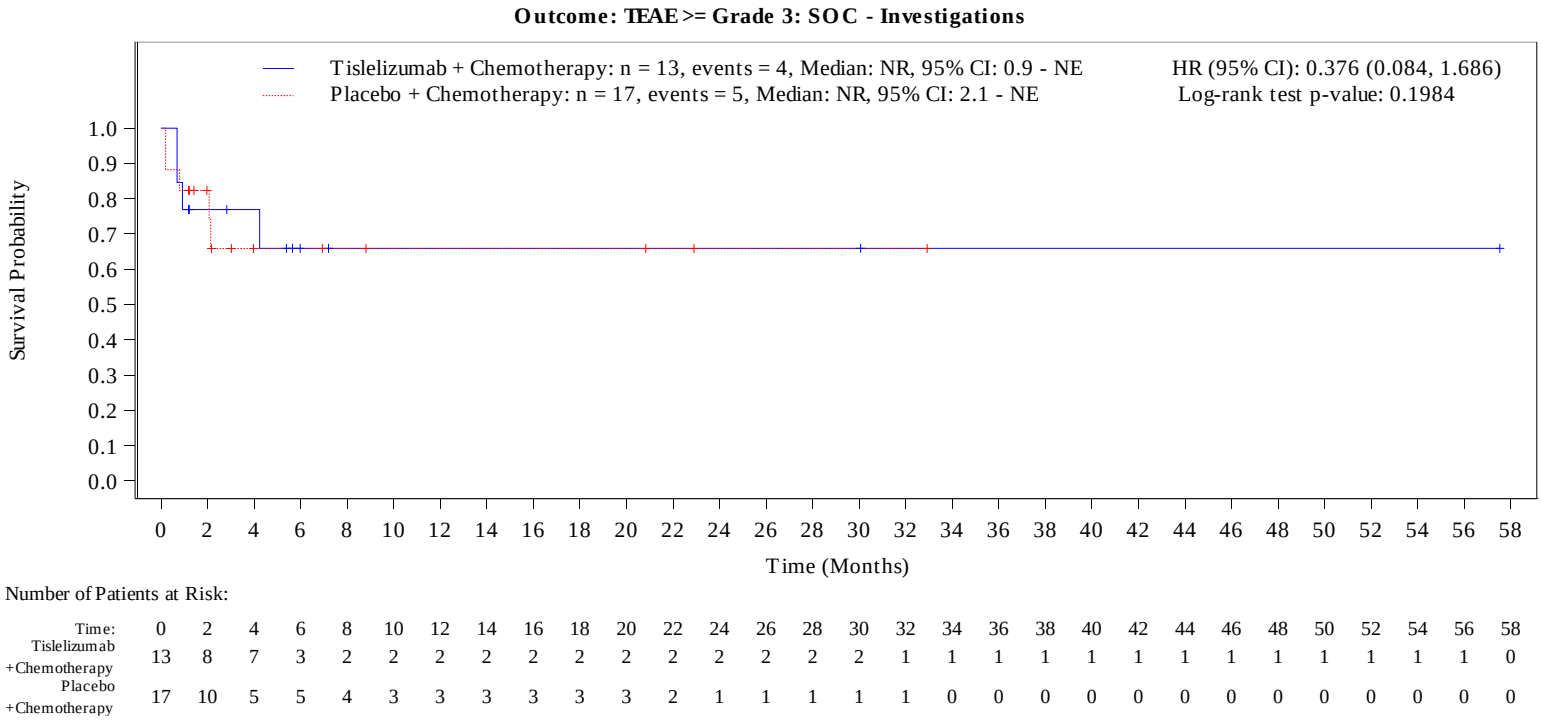

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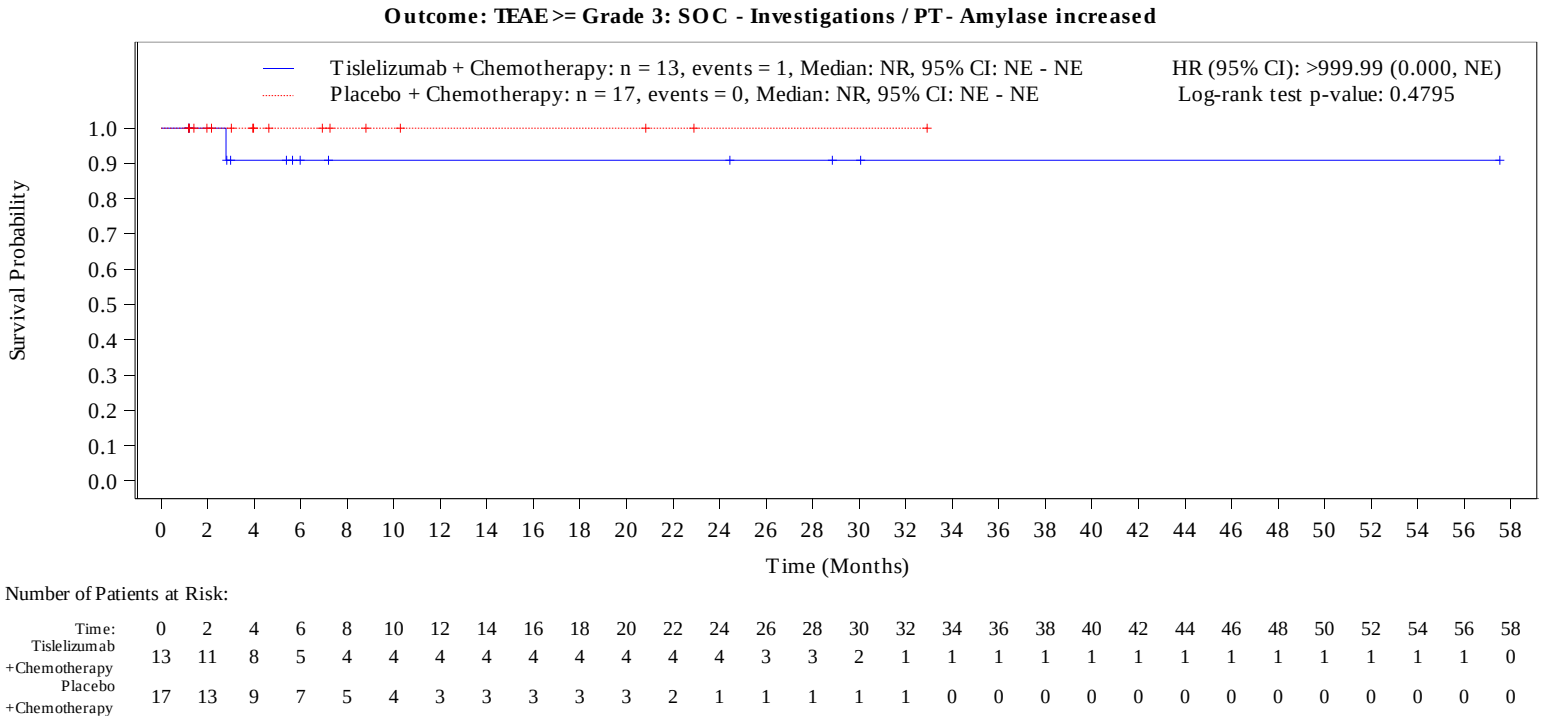

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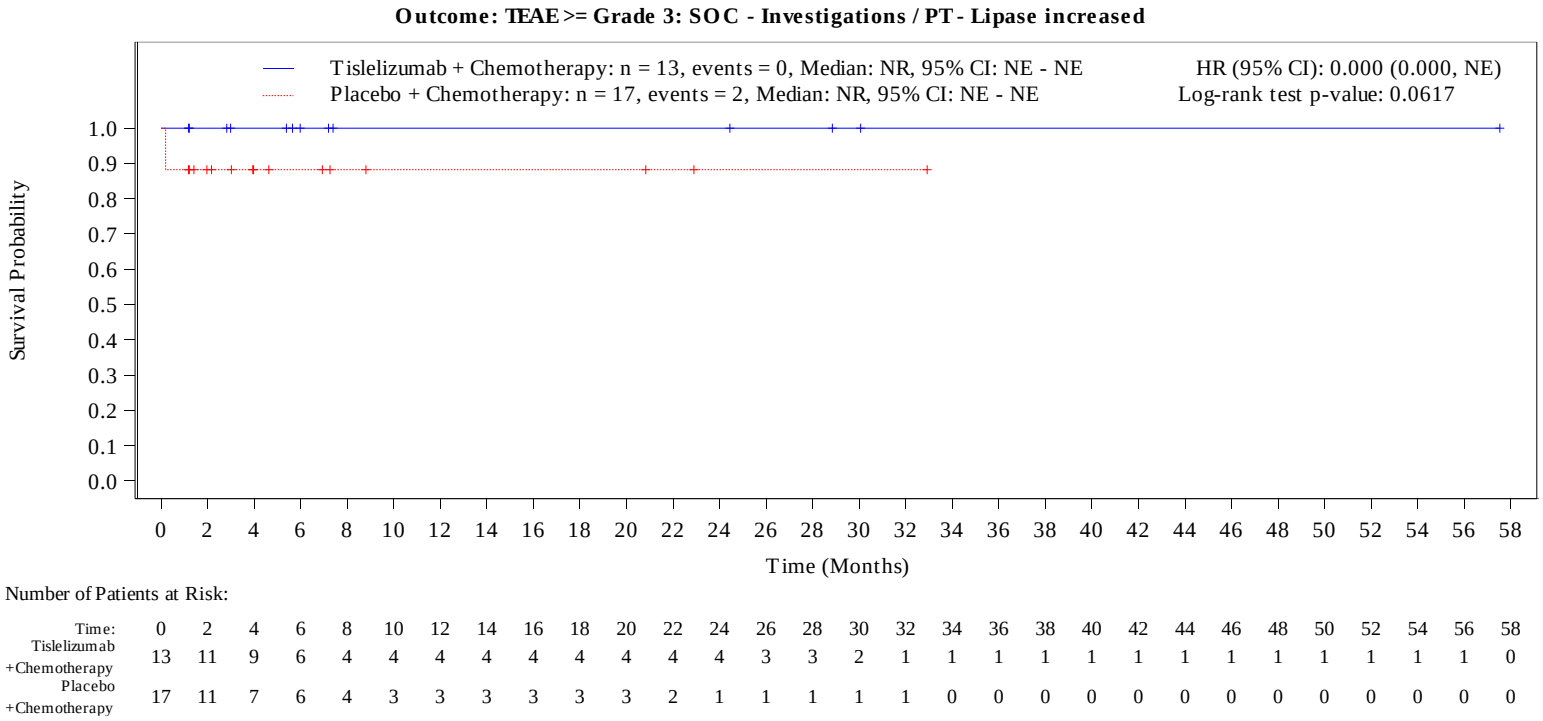

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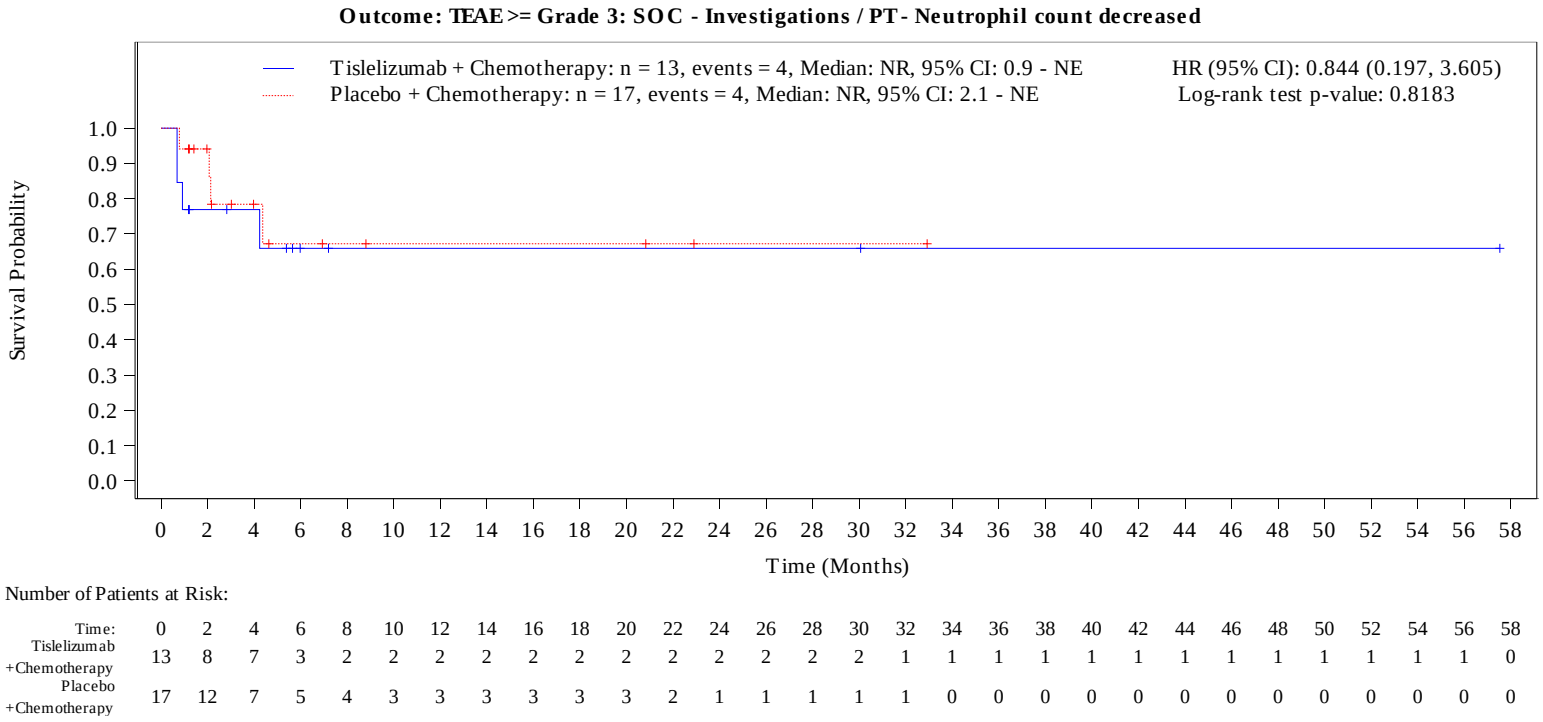

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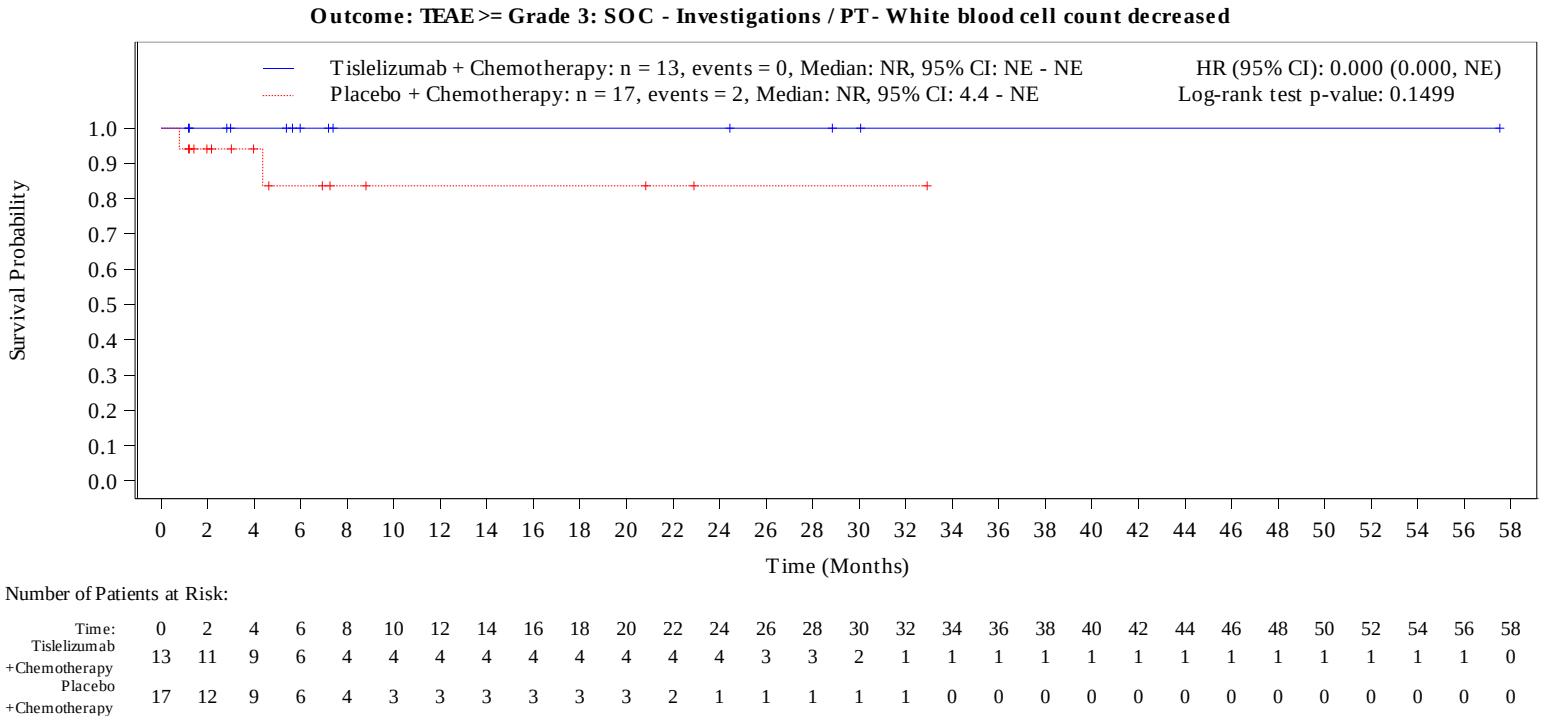

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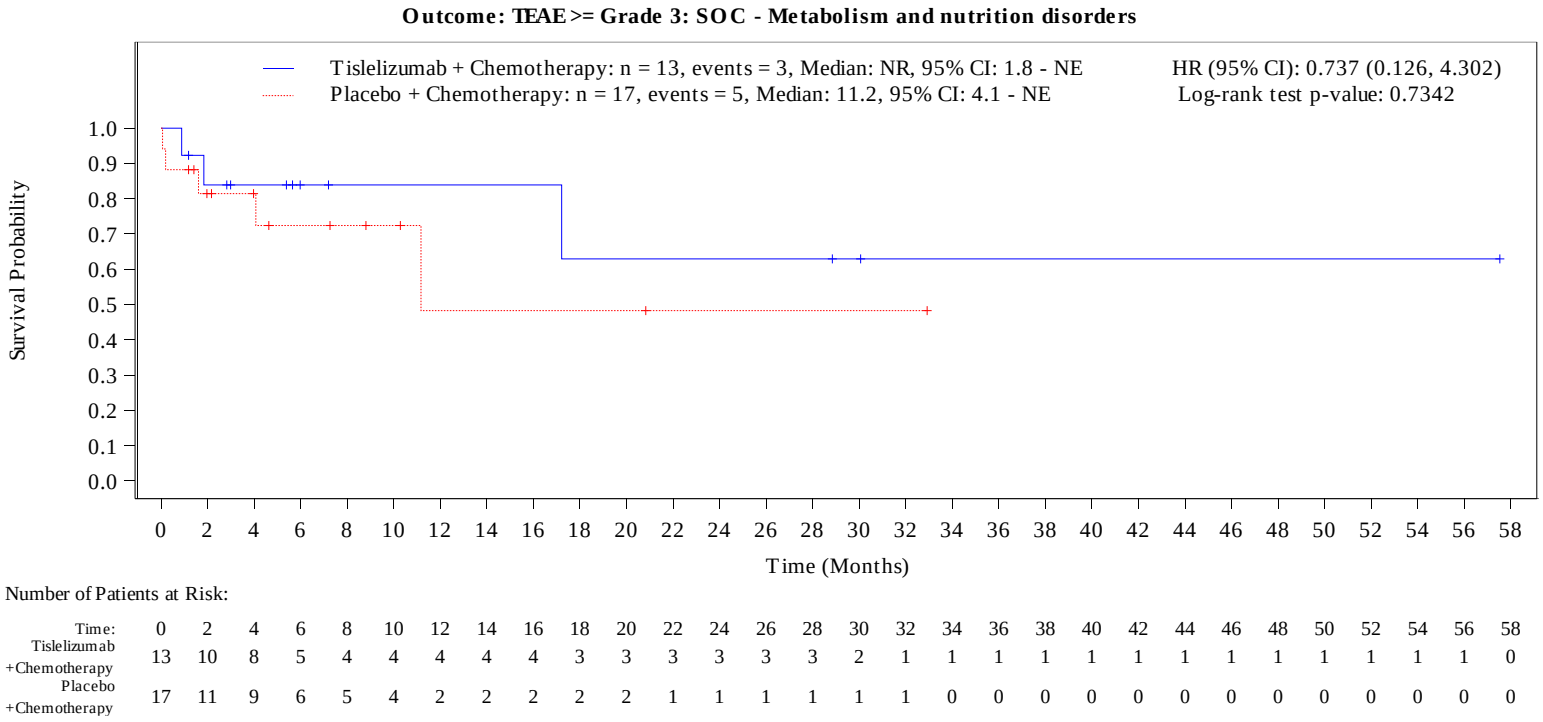

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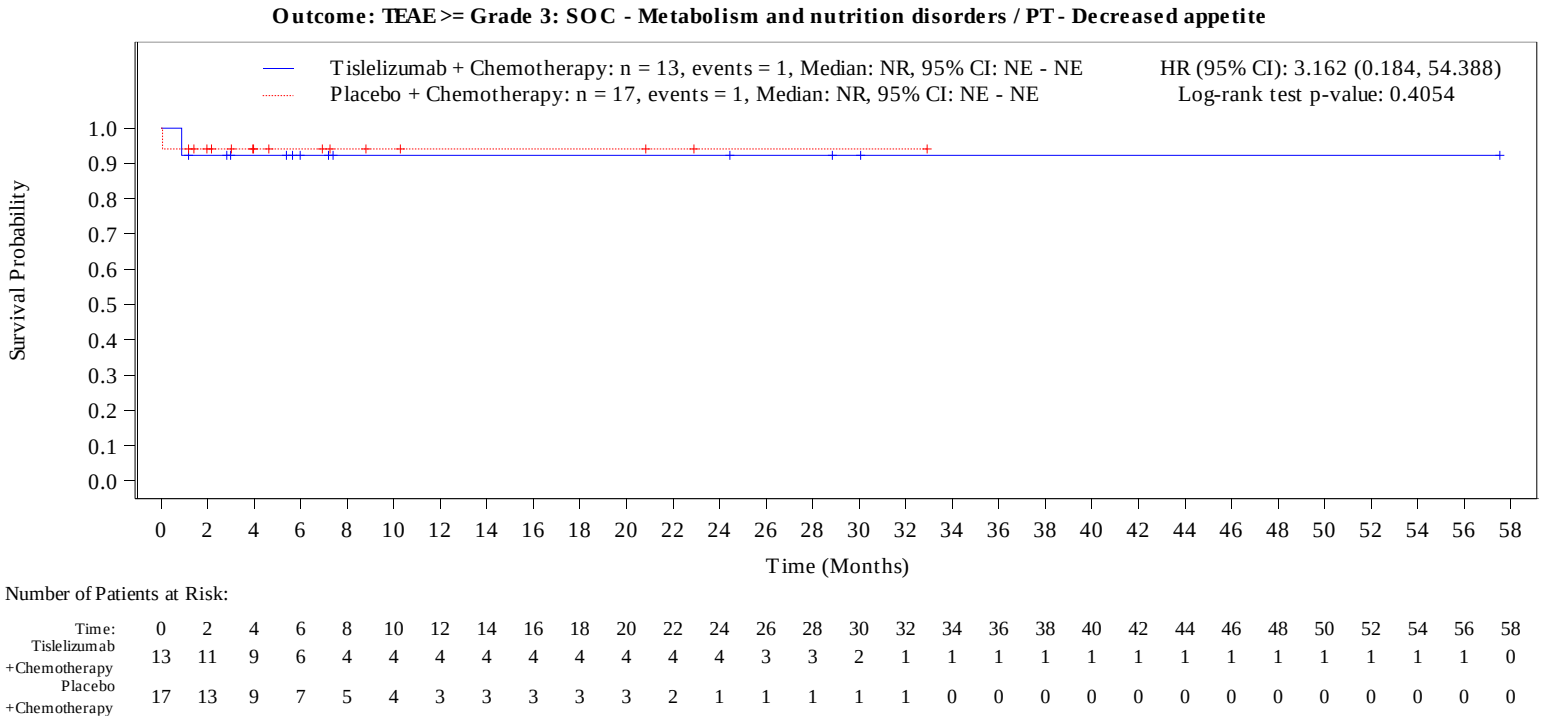

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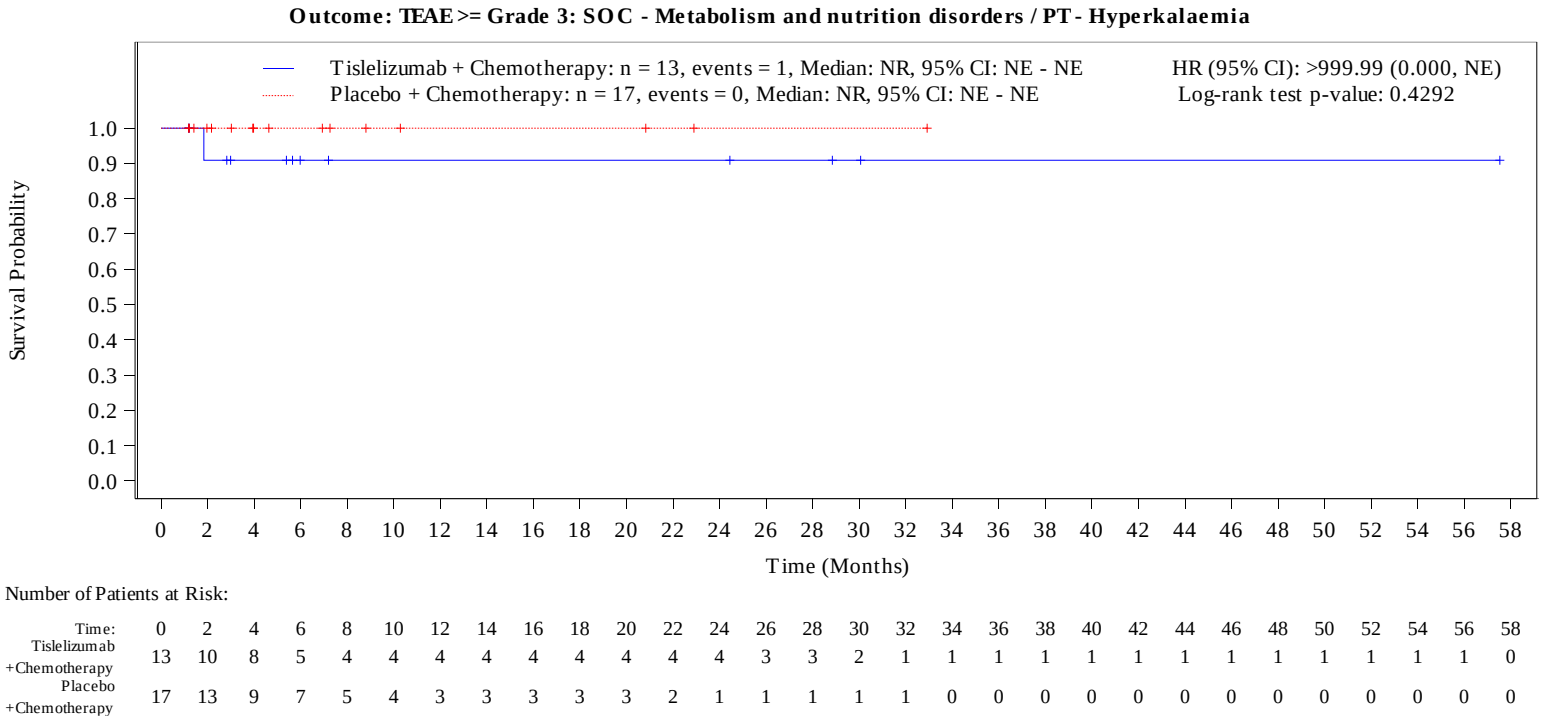

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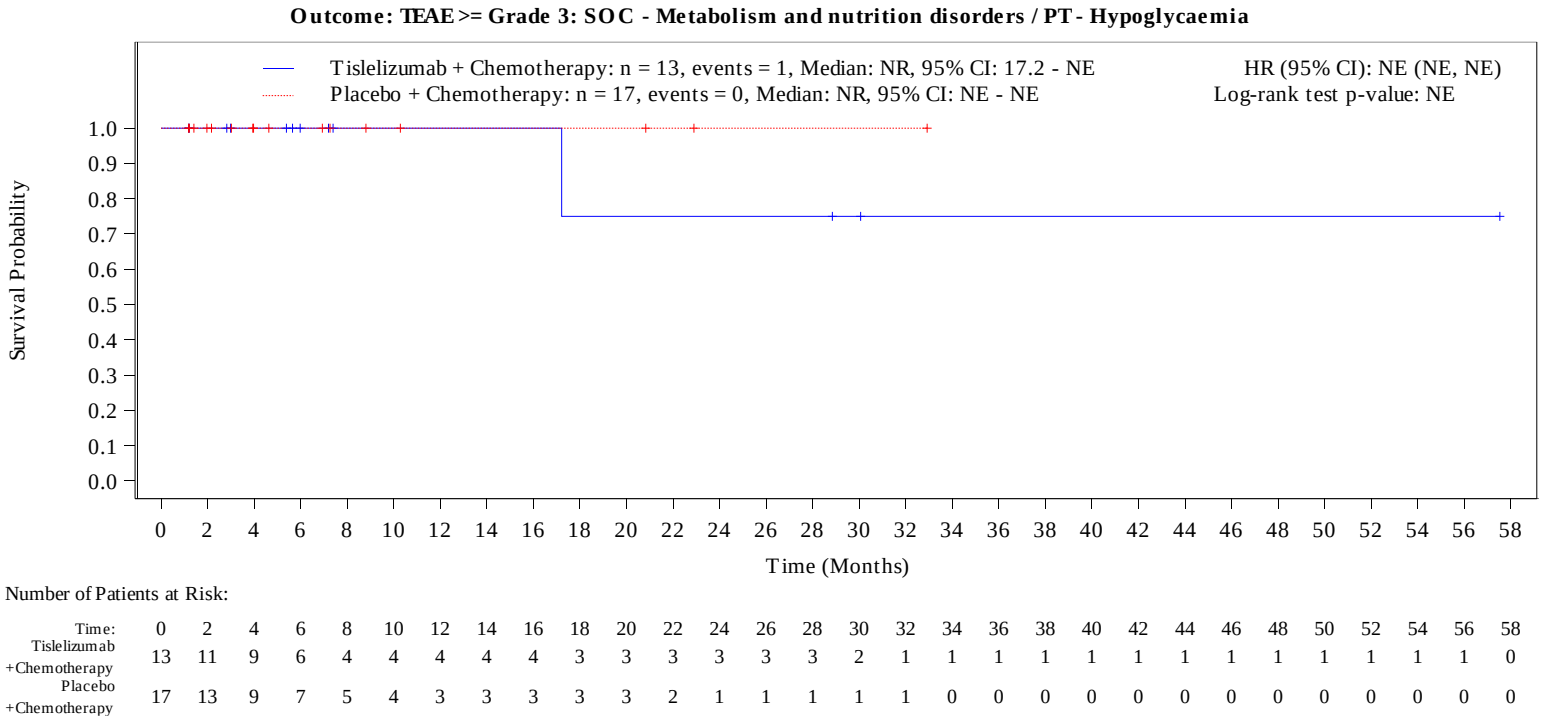

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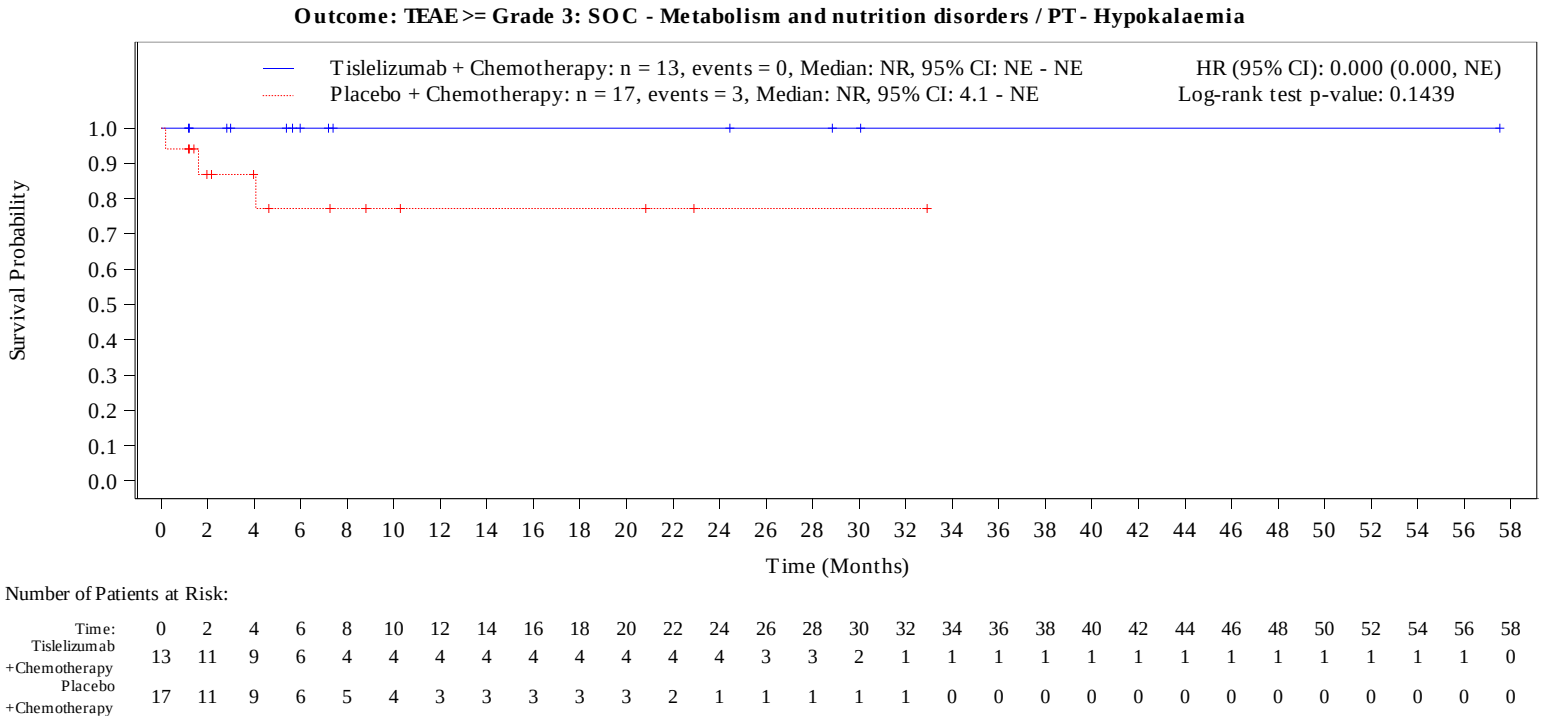

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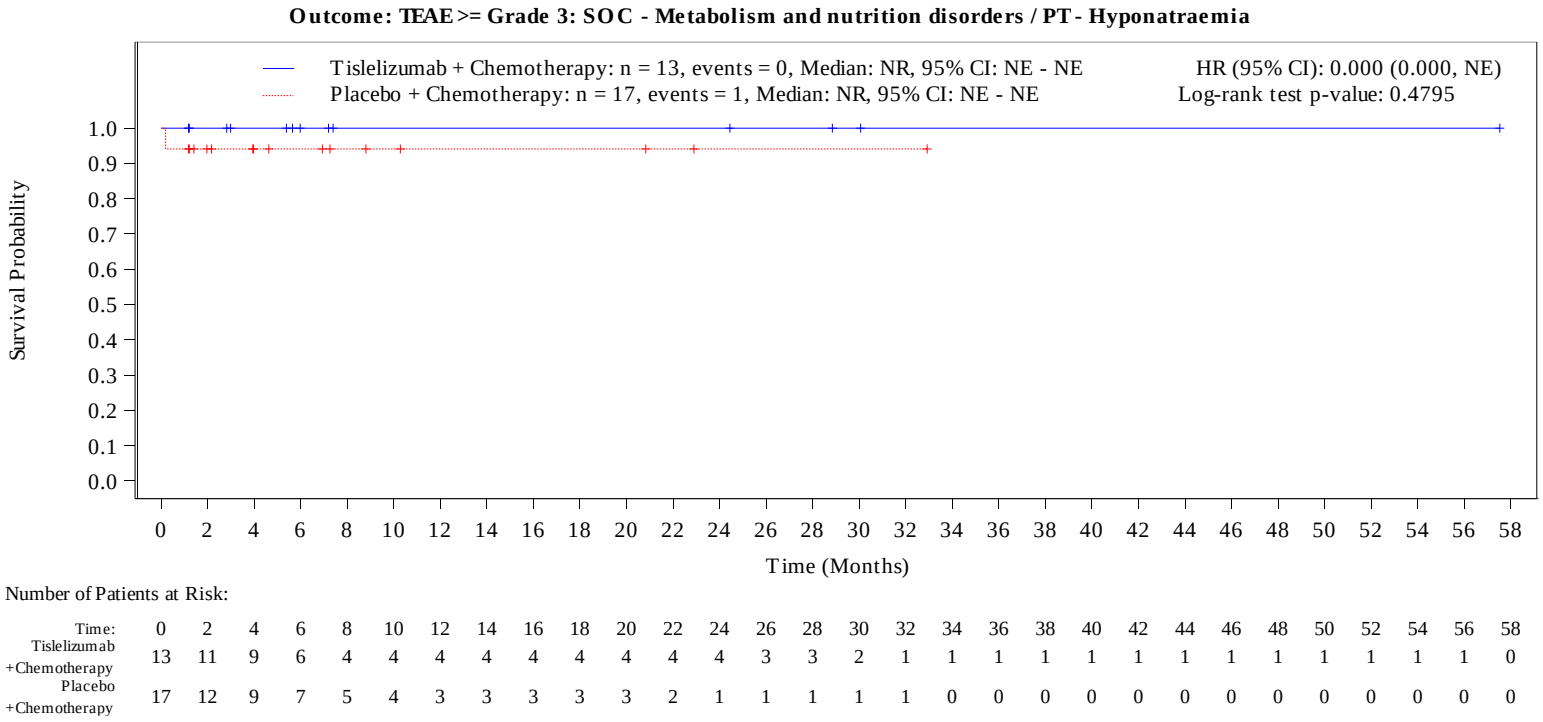

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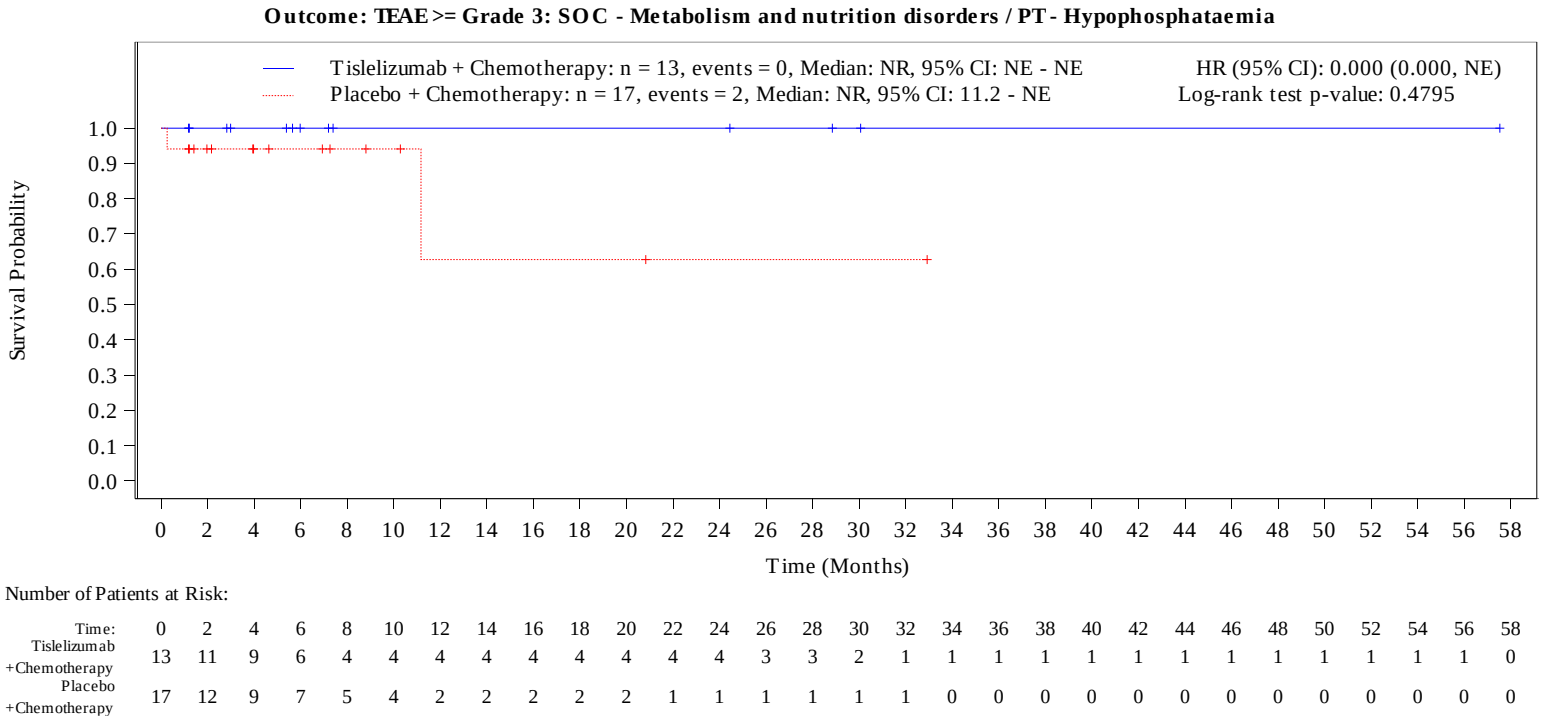

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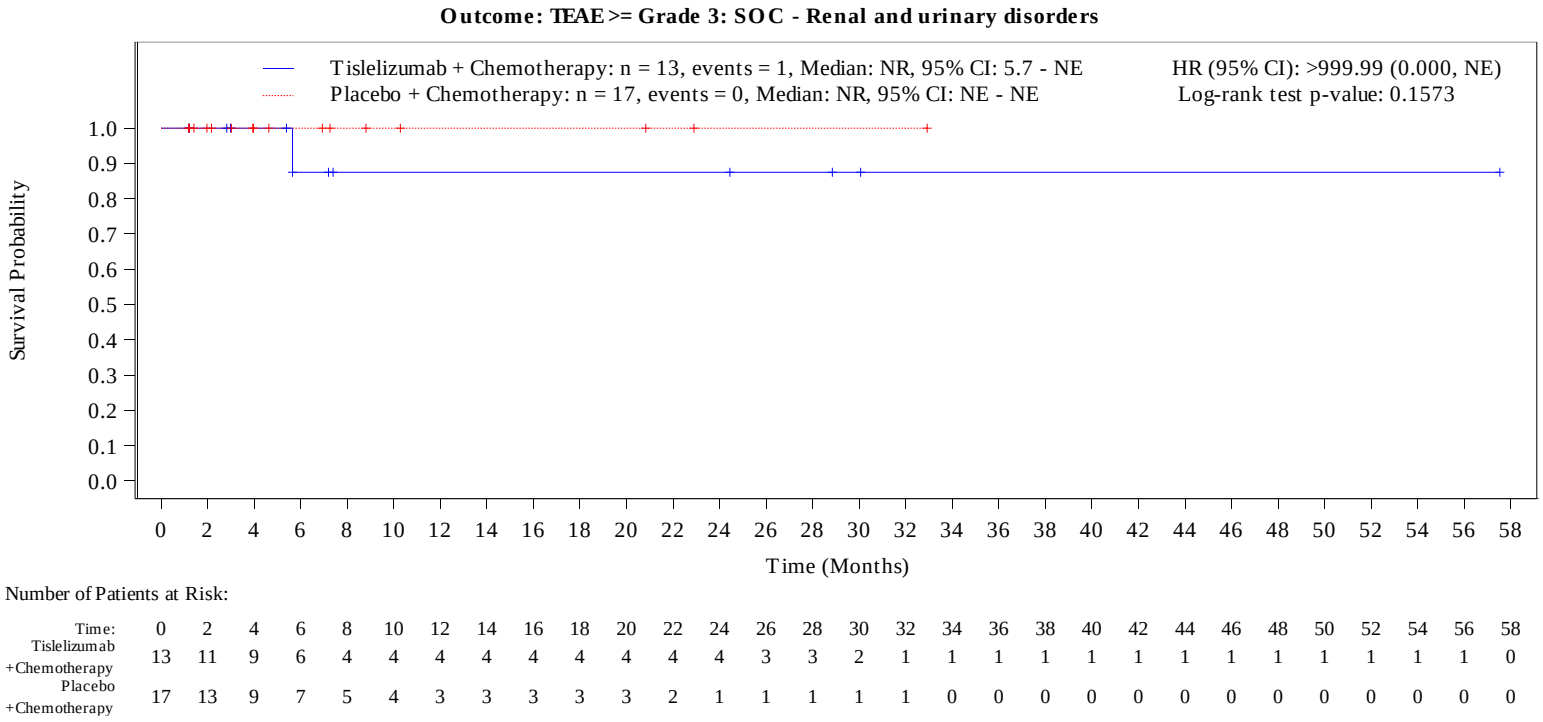
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

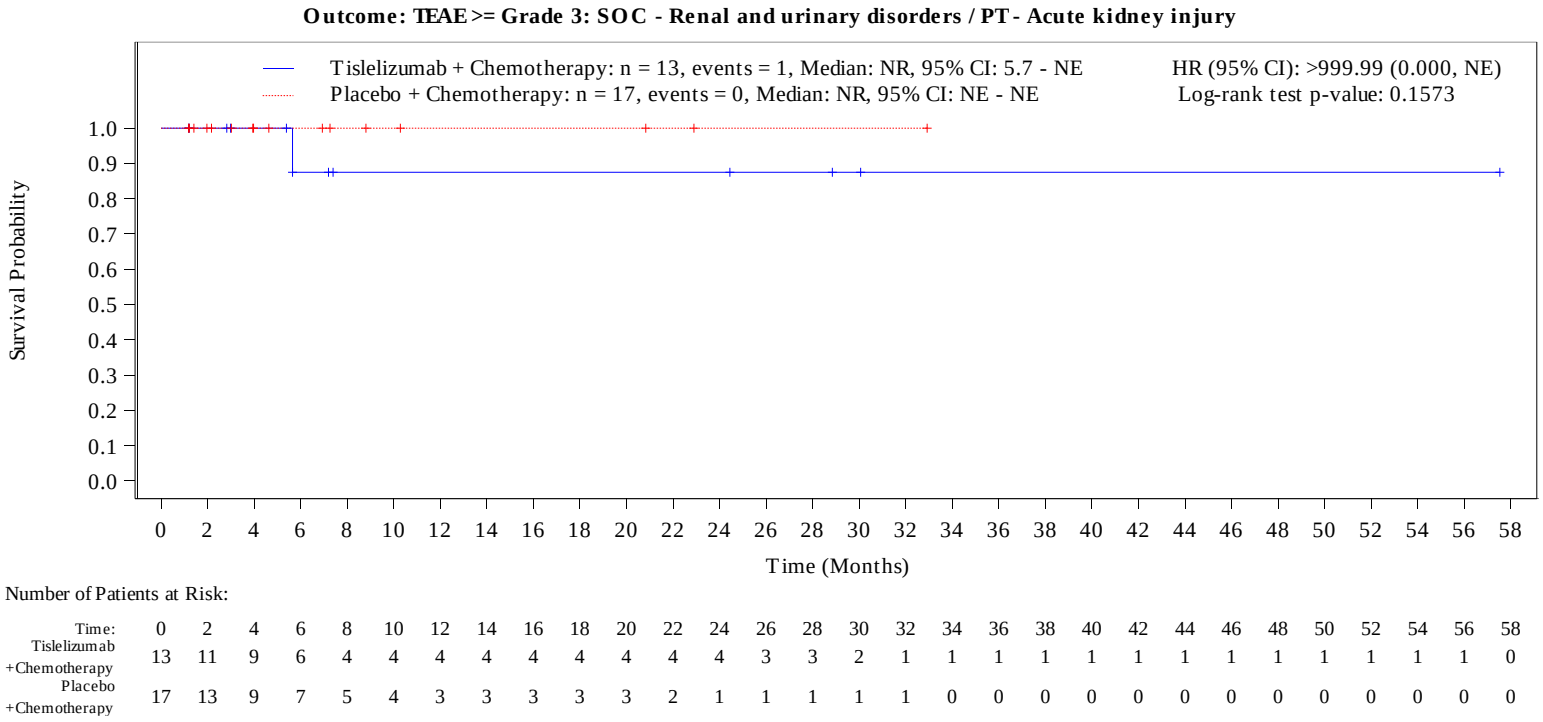

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

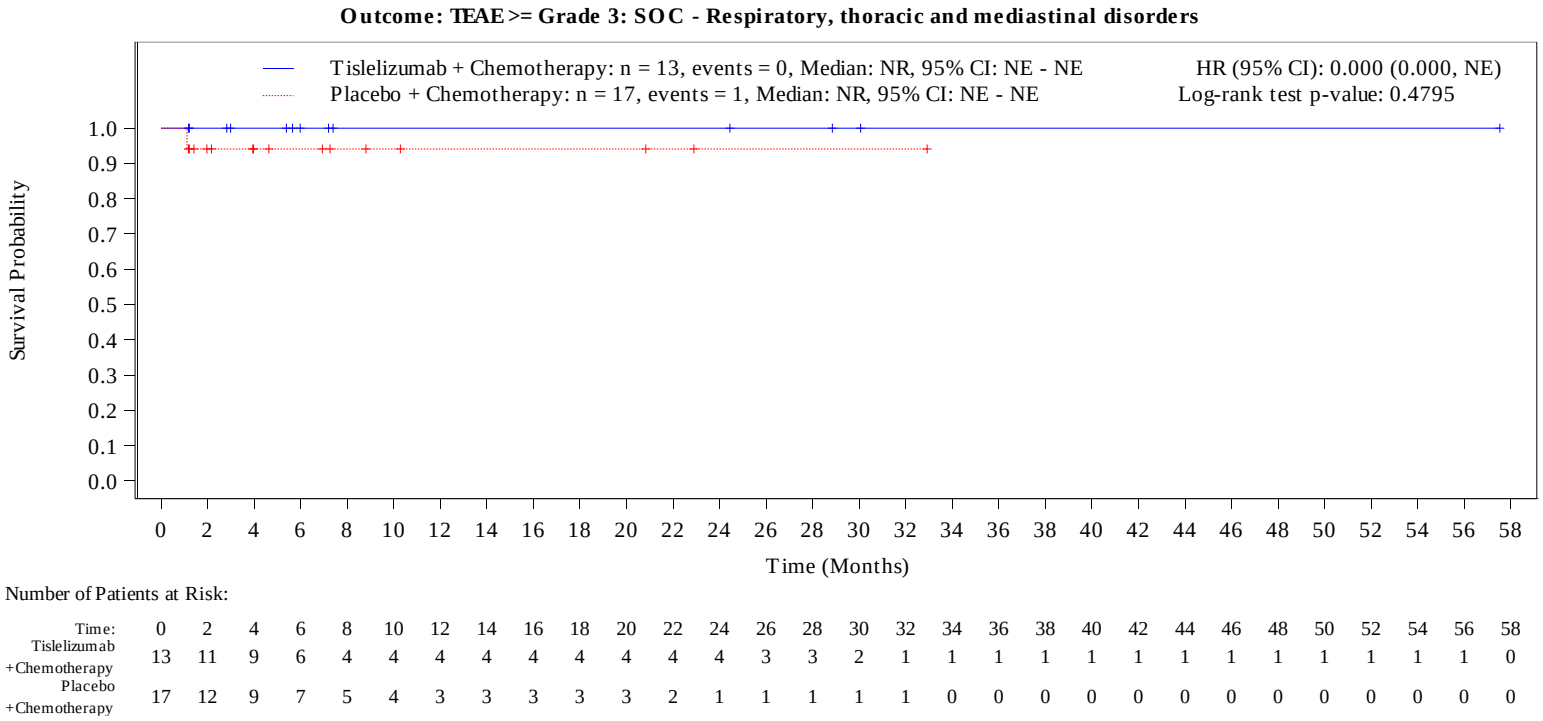

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

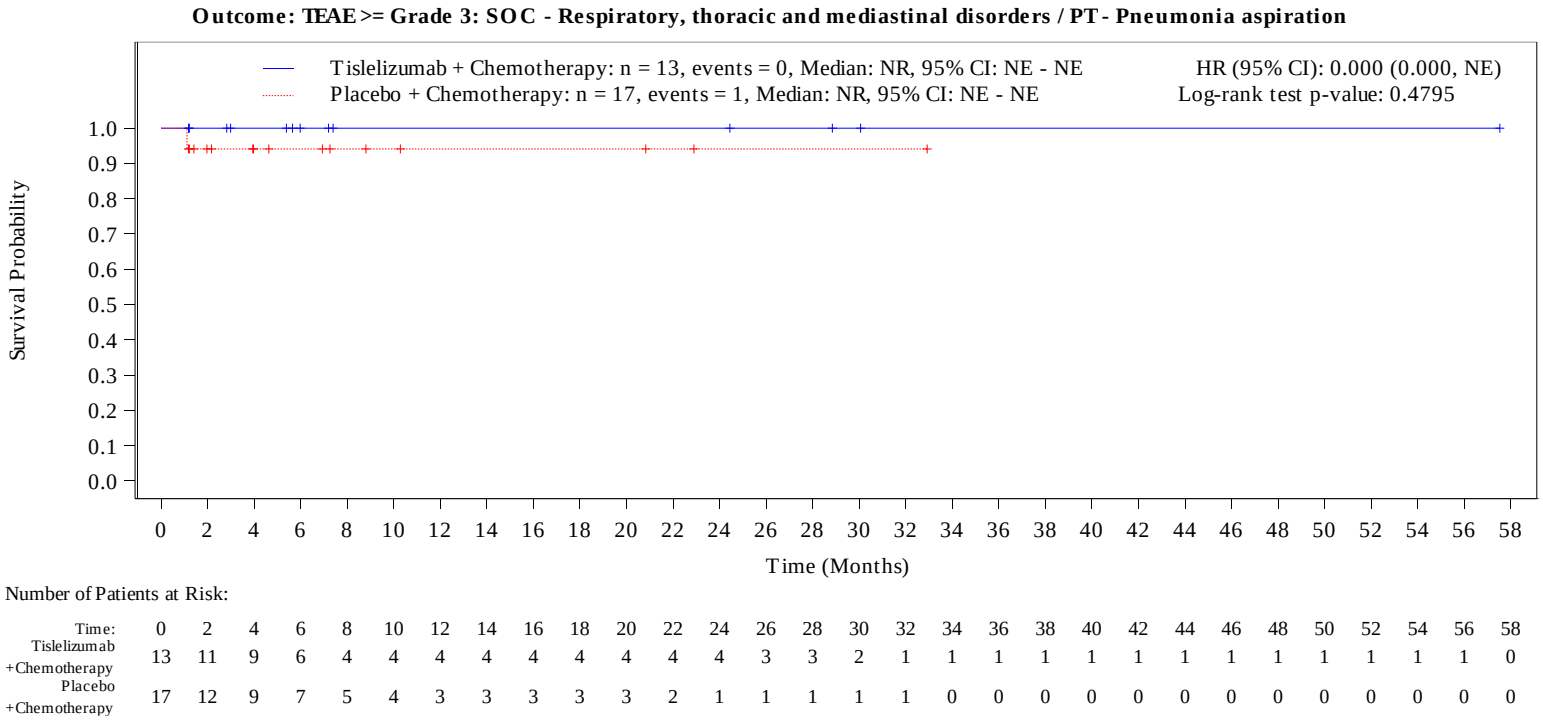

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Figure 14.3.1.3:
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Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

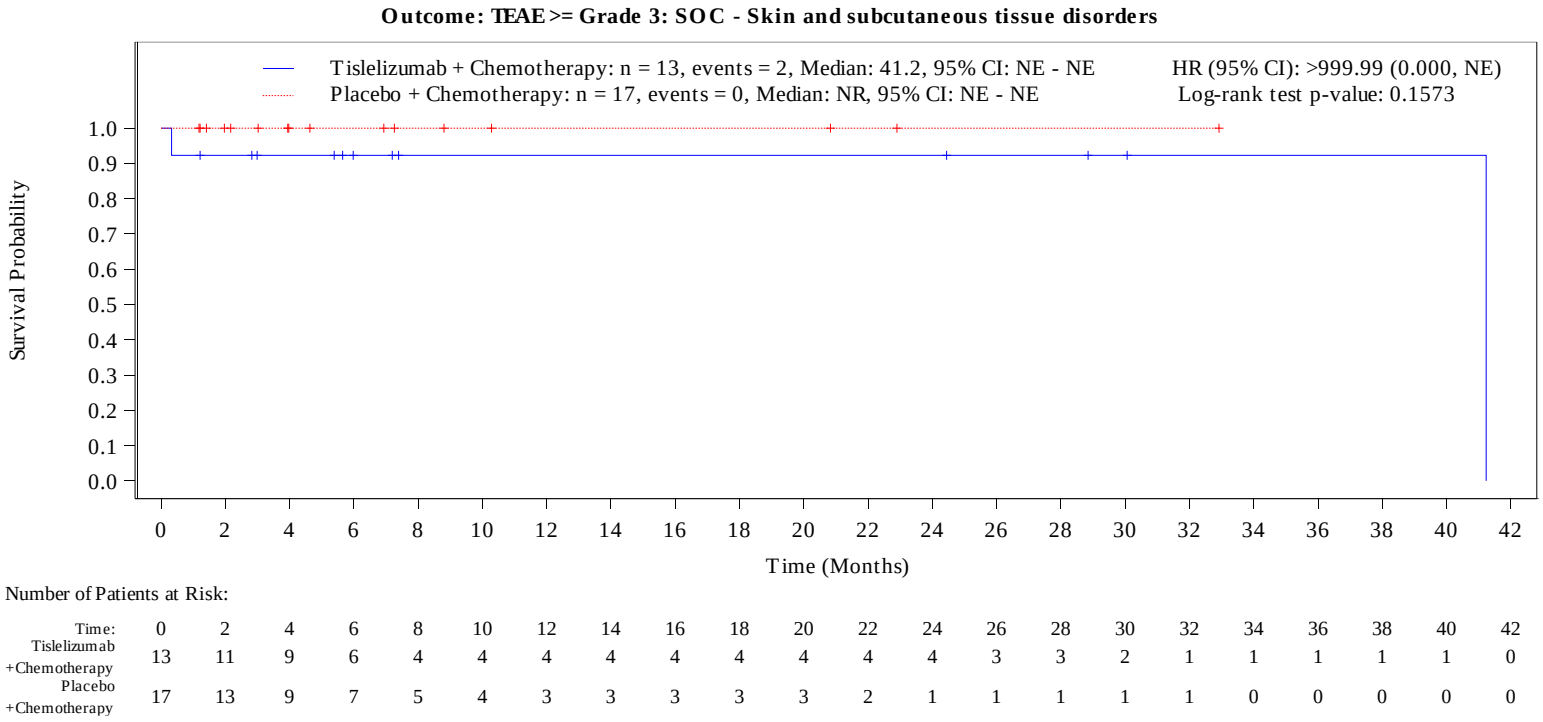

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Figure 14.3.1.3:
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Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

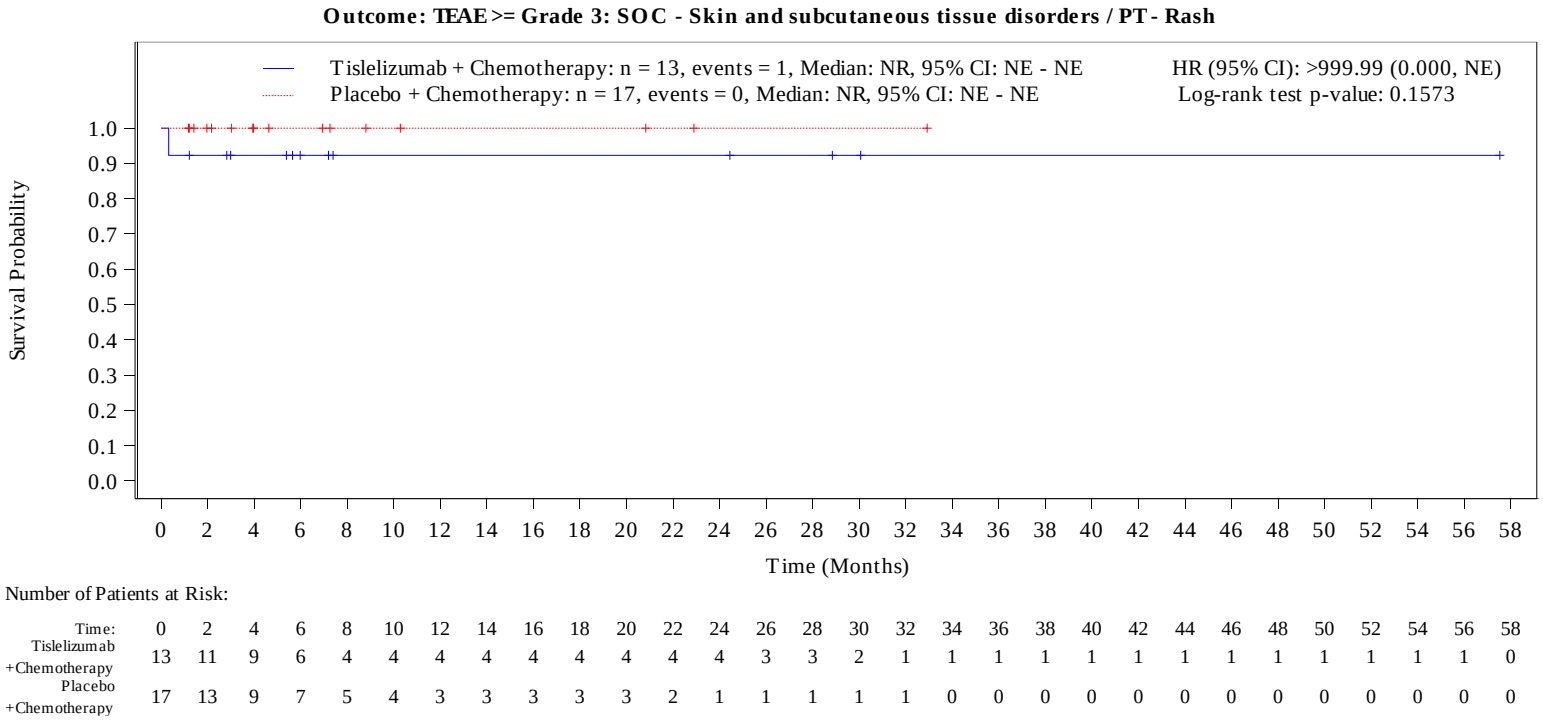

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Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

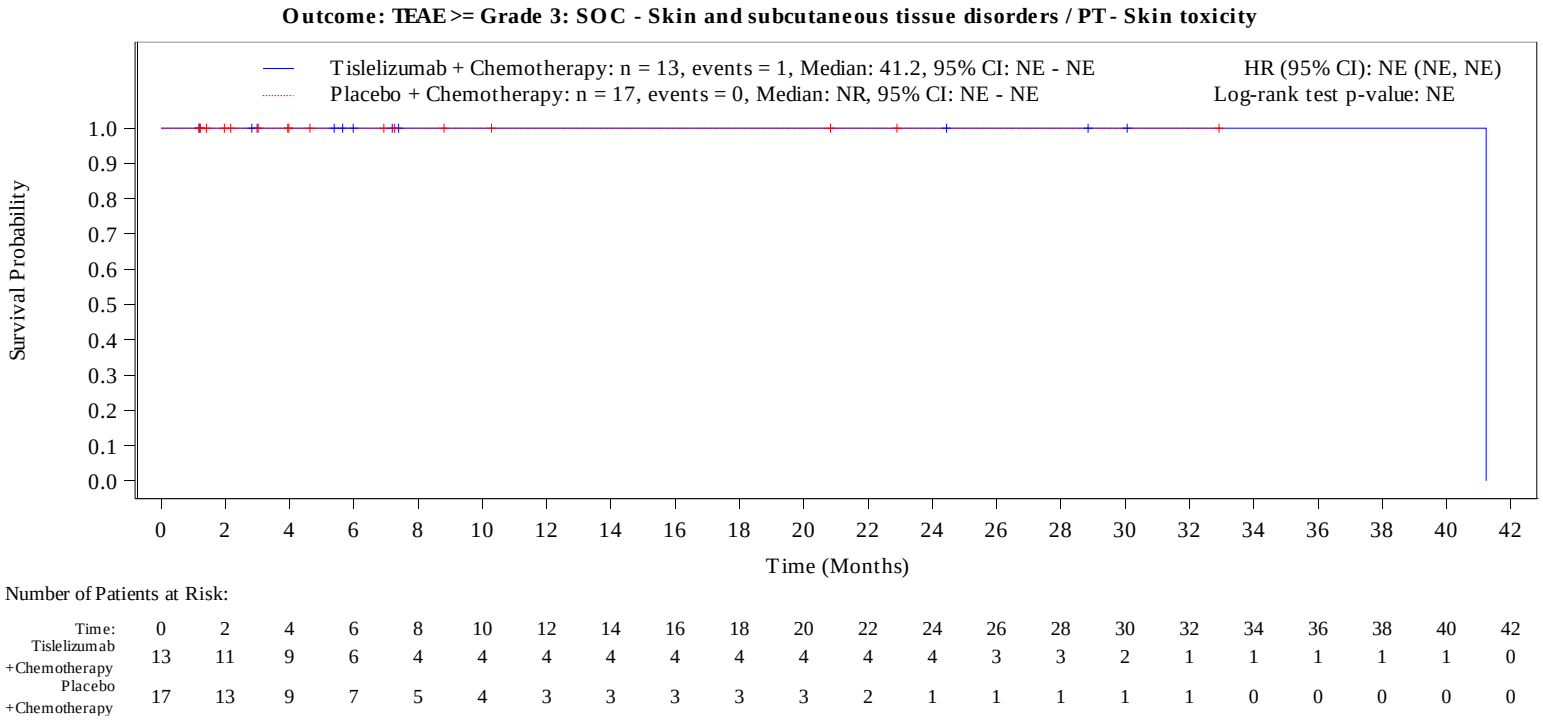

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

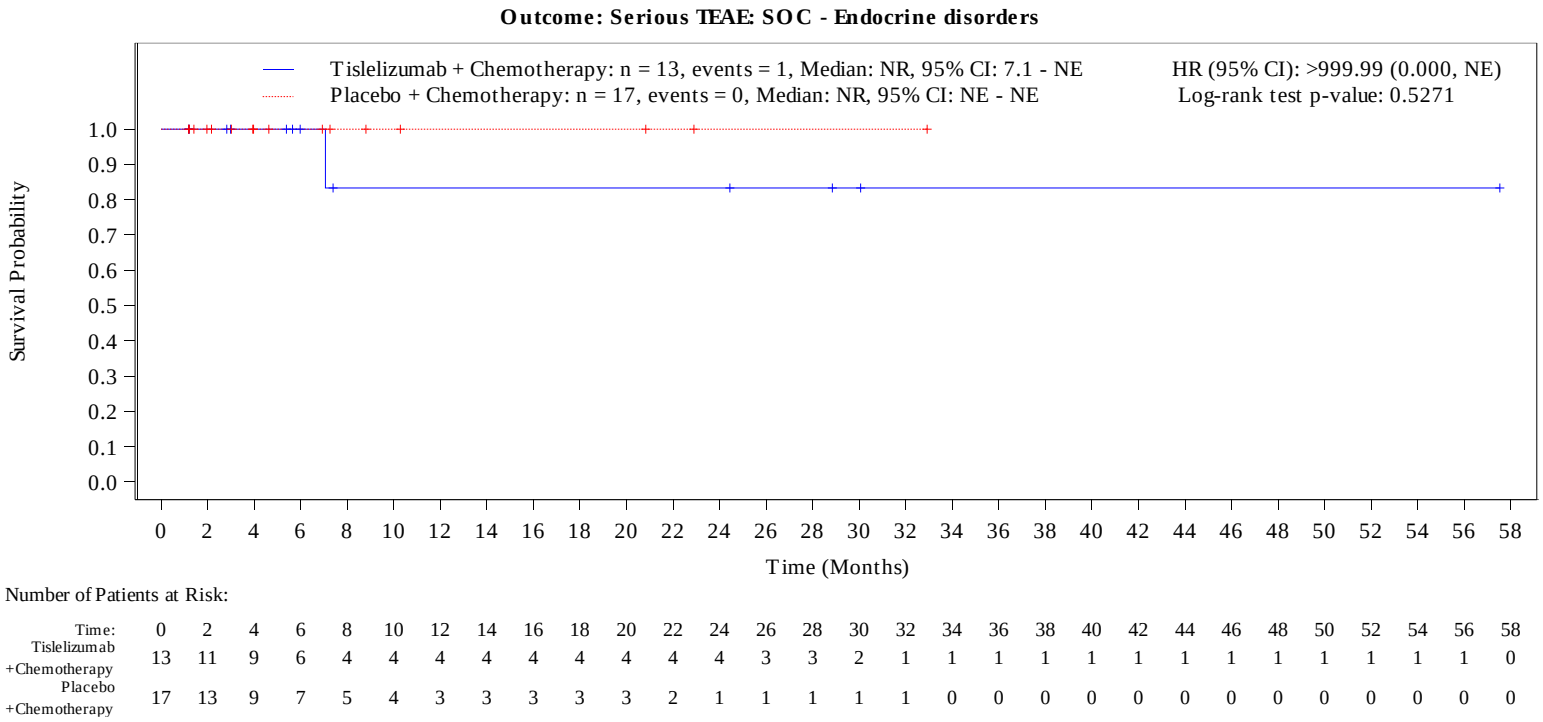

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

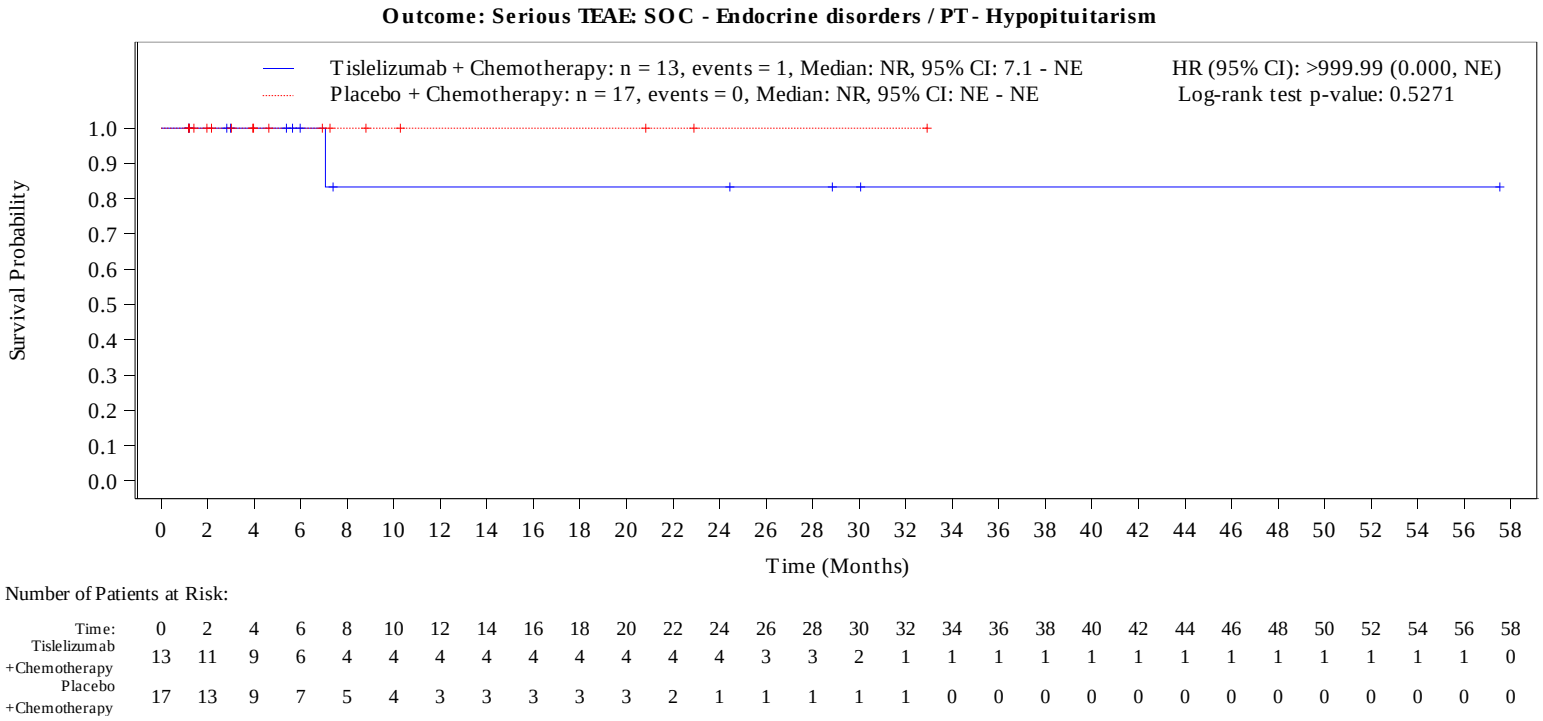

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

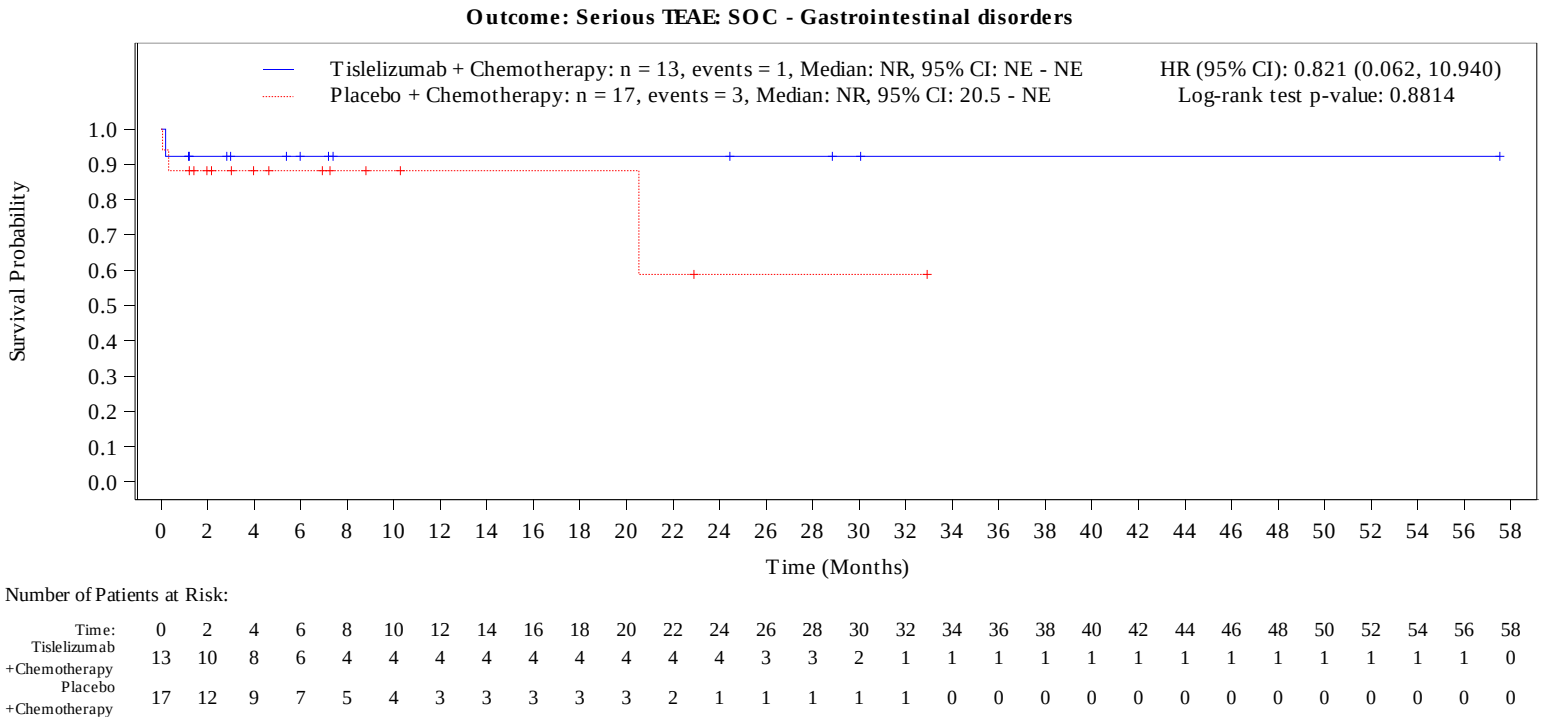

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

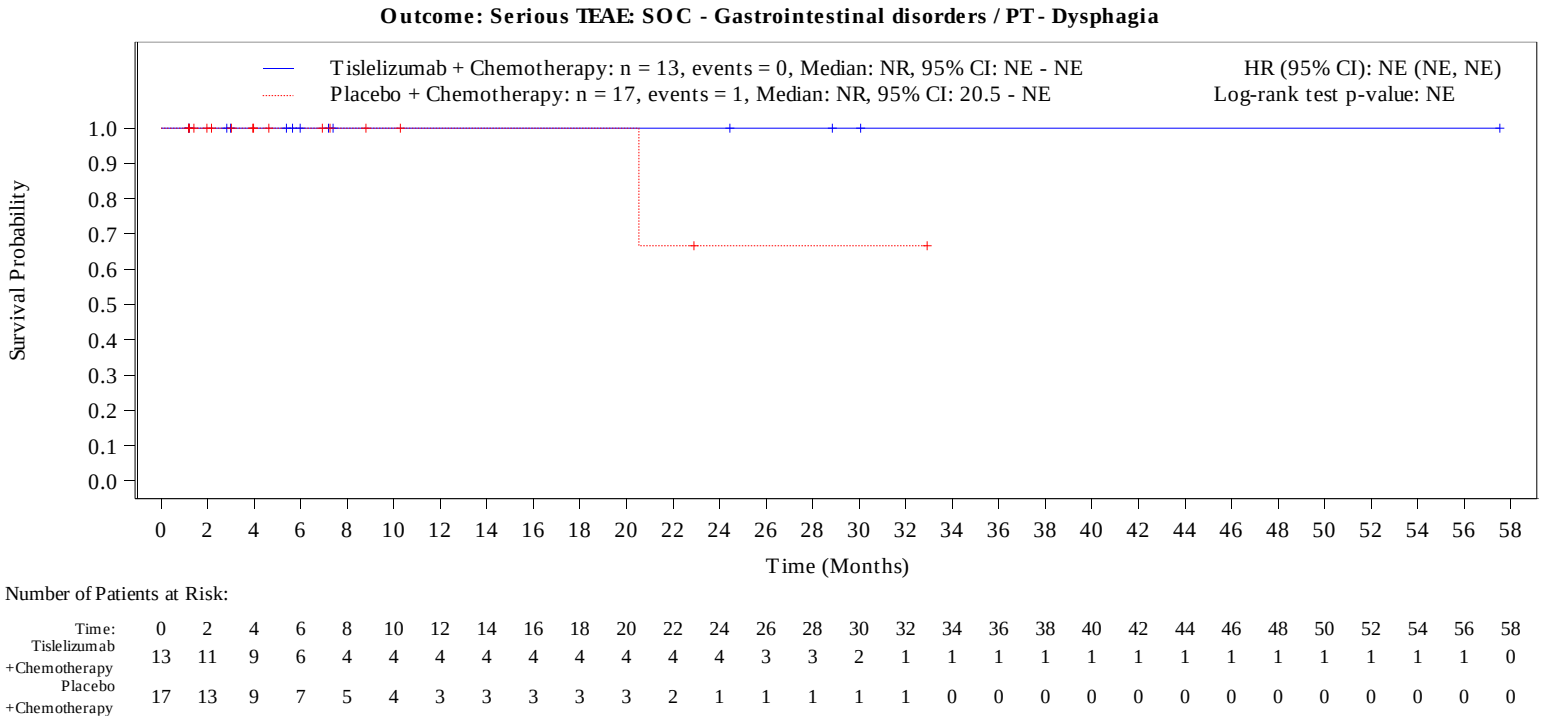

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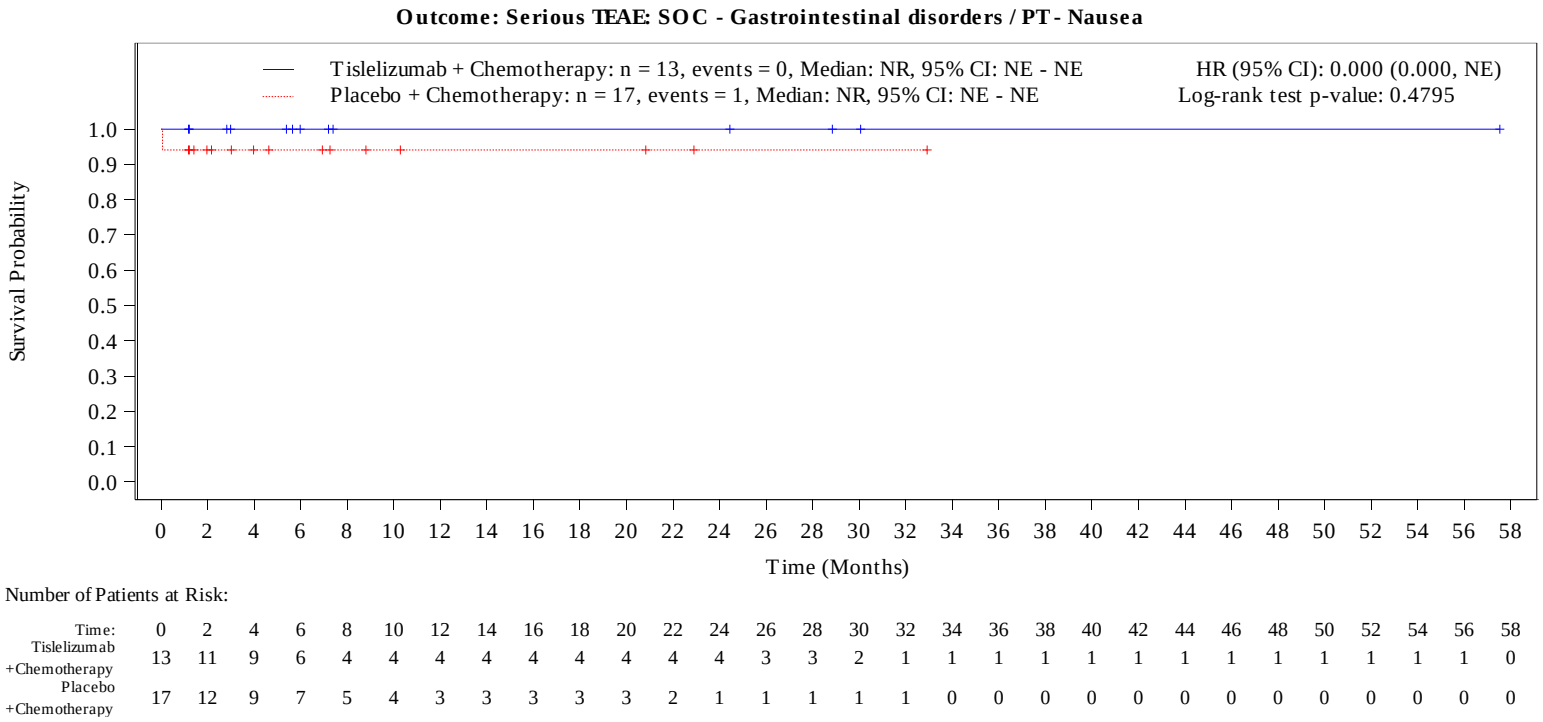
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

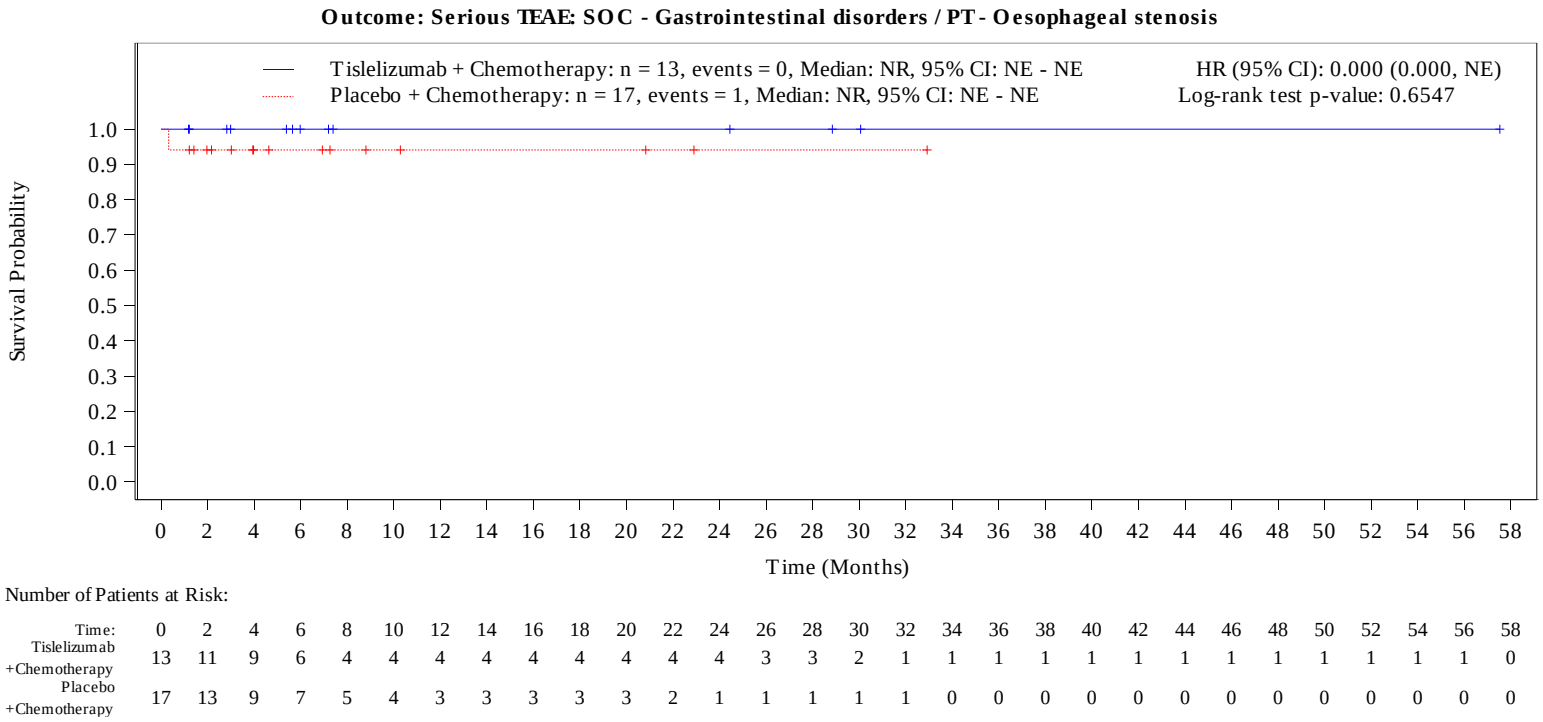

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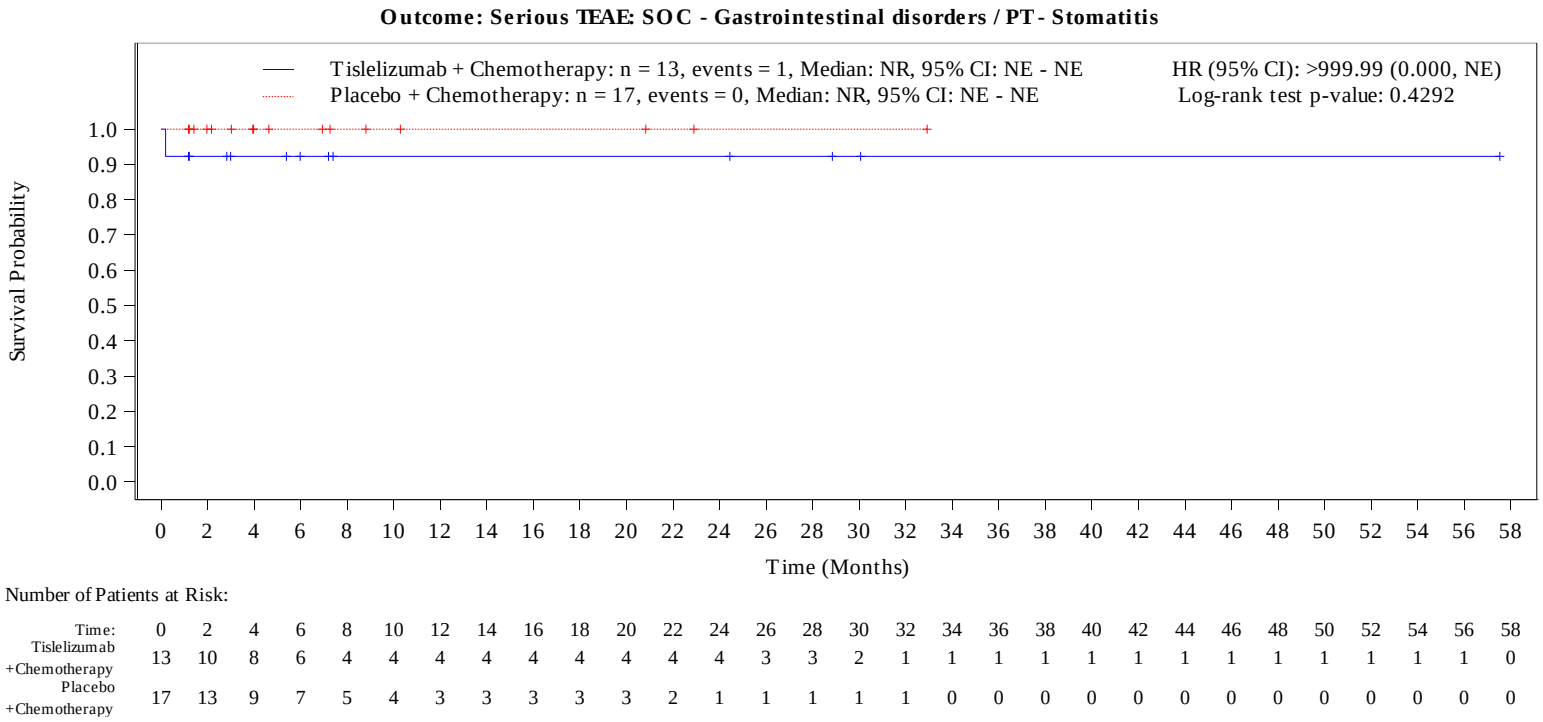
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	10	8	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

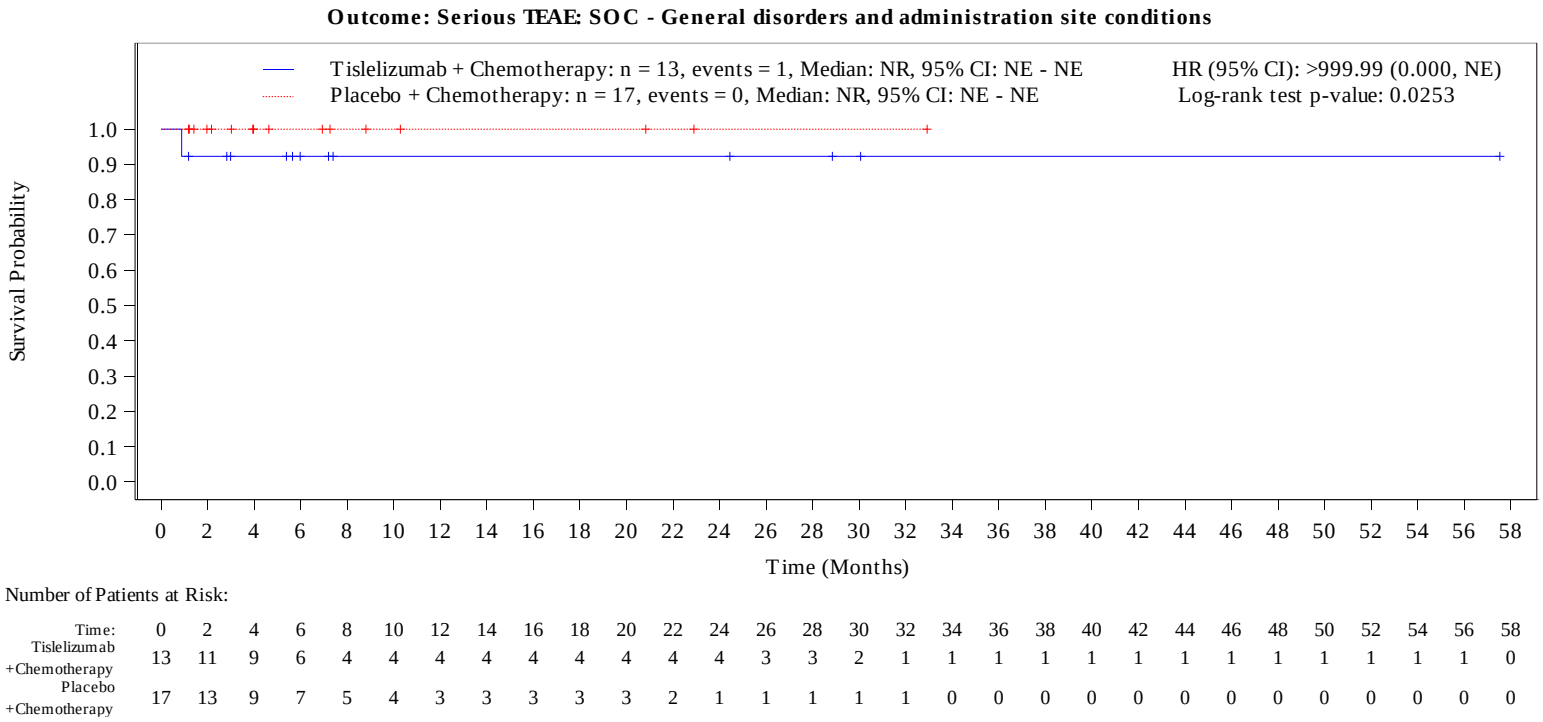

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Figure 14.3.1.4:
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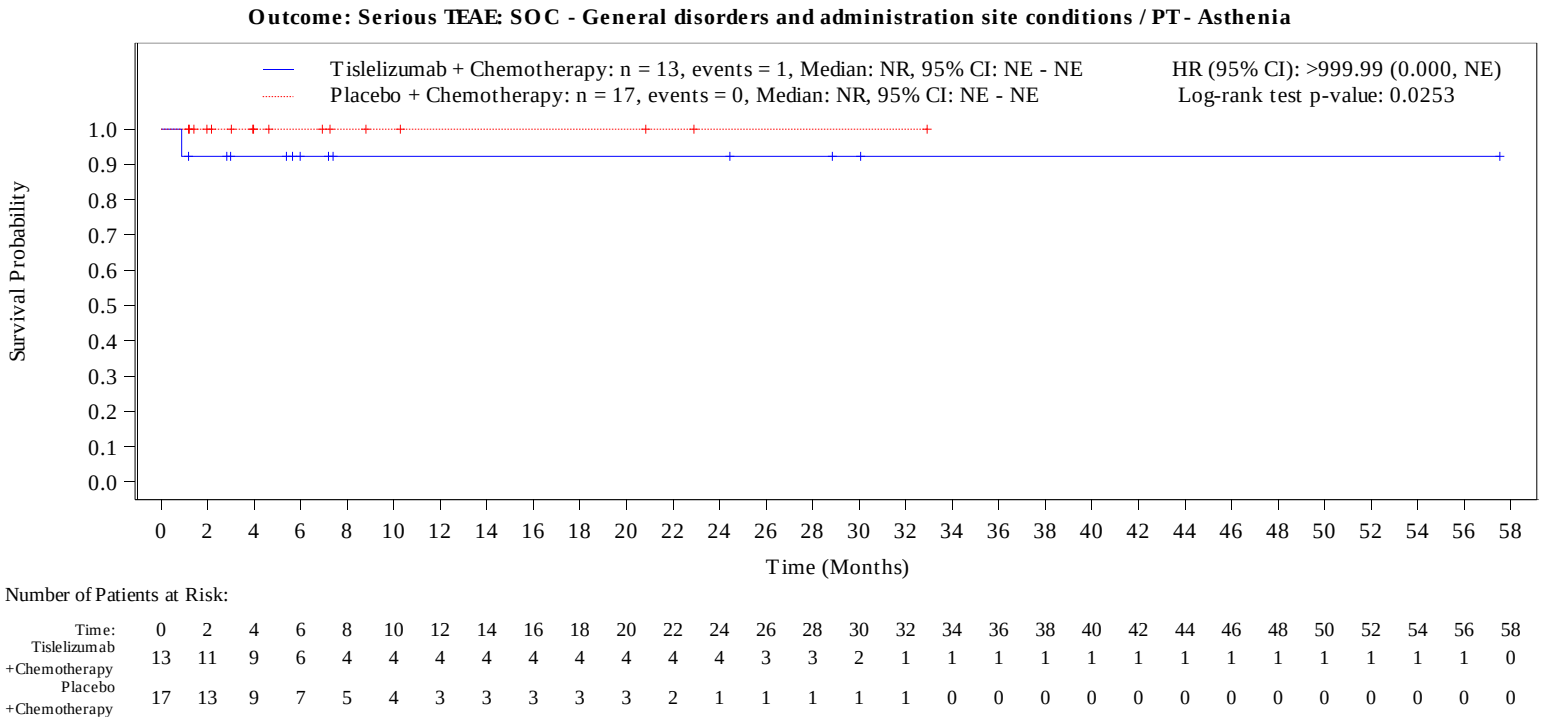

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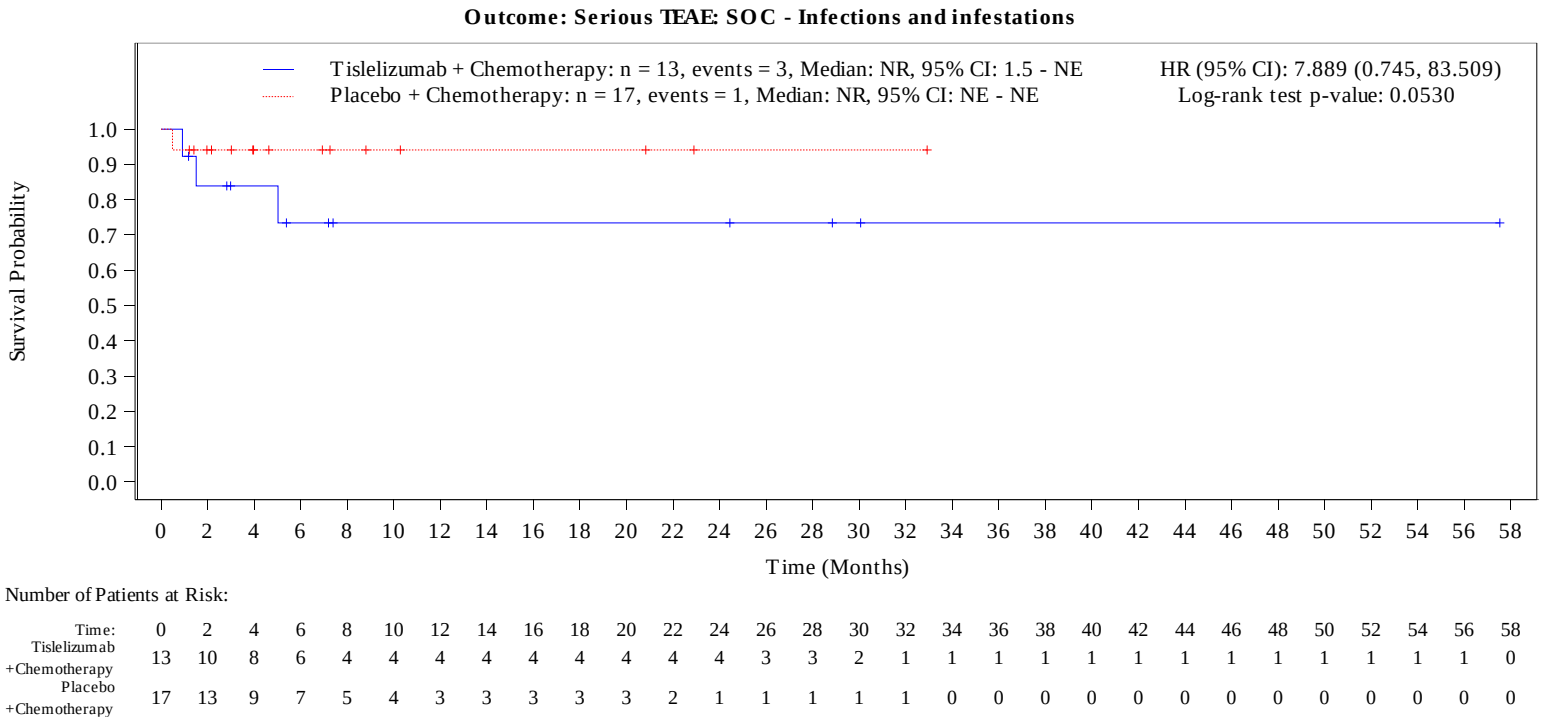

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Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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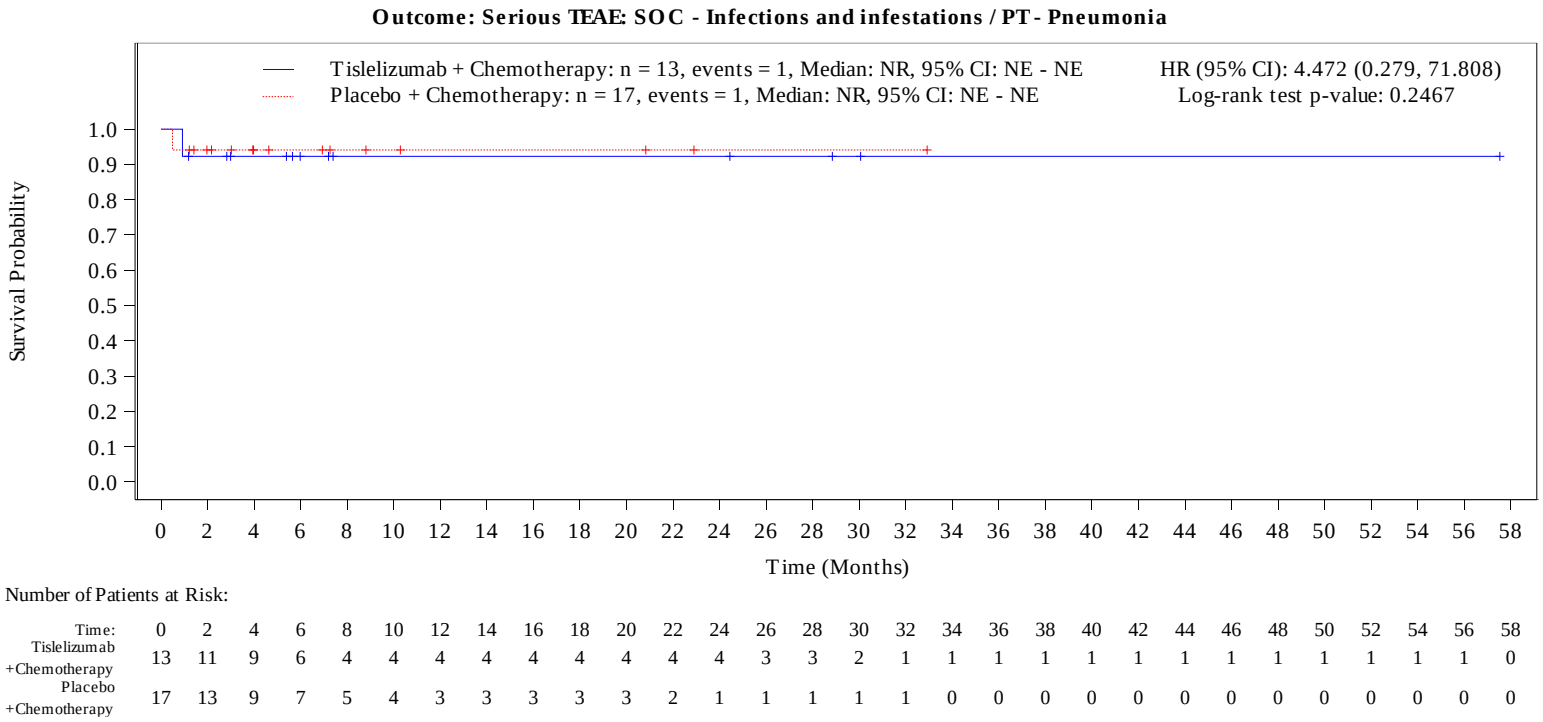

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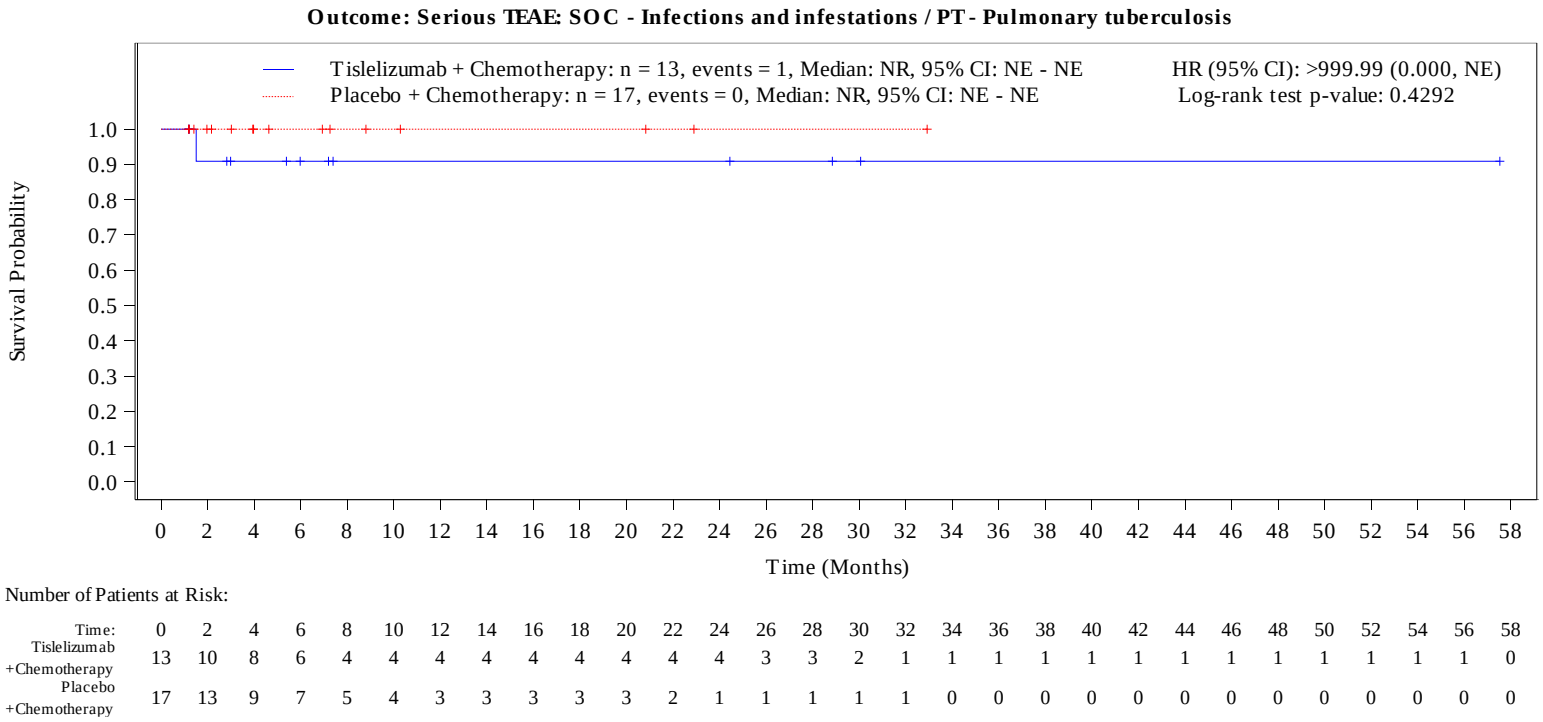

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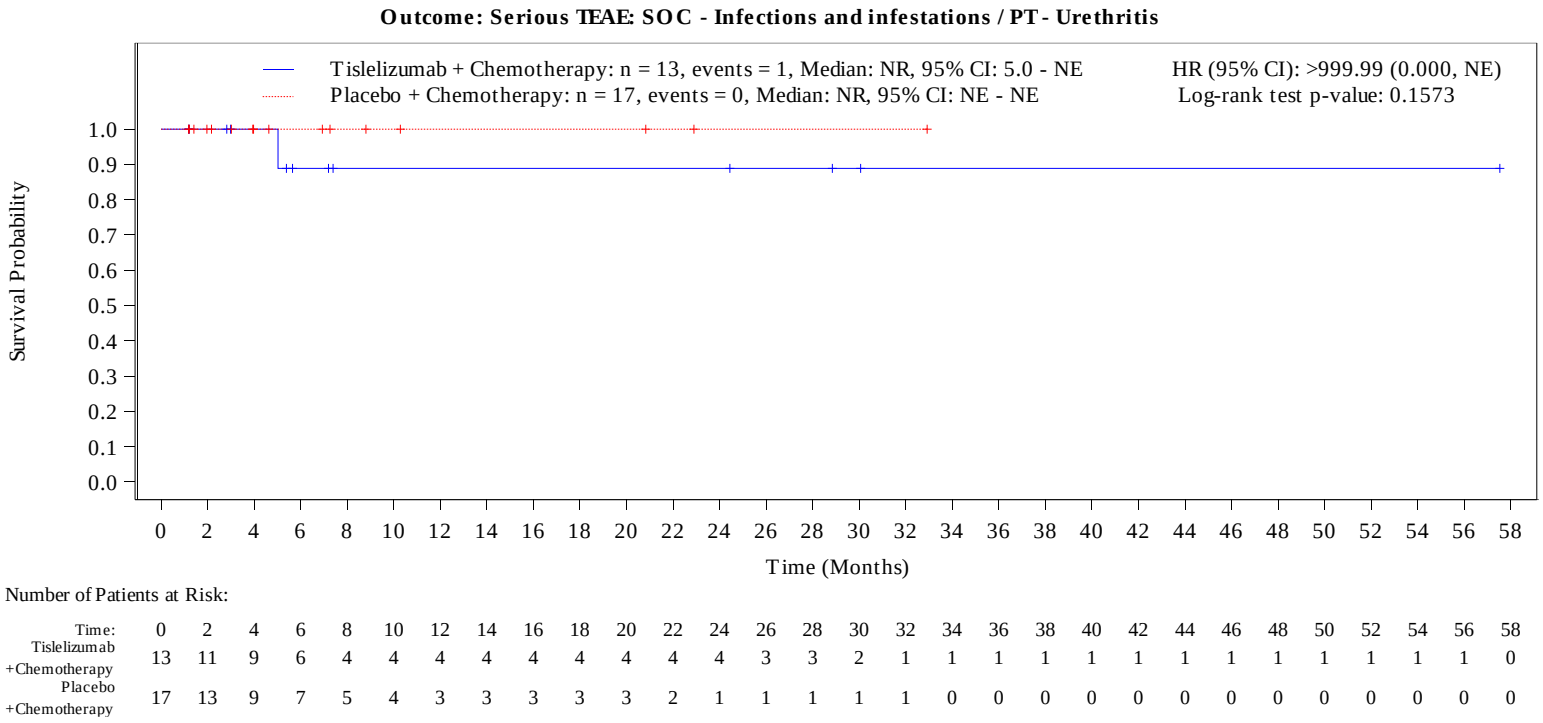
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI was based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-aesocpt.sas 14NOV2024 06:03 f-14-3-1-4-km-aesocpt-ser-pop1-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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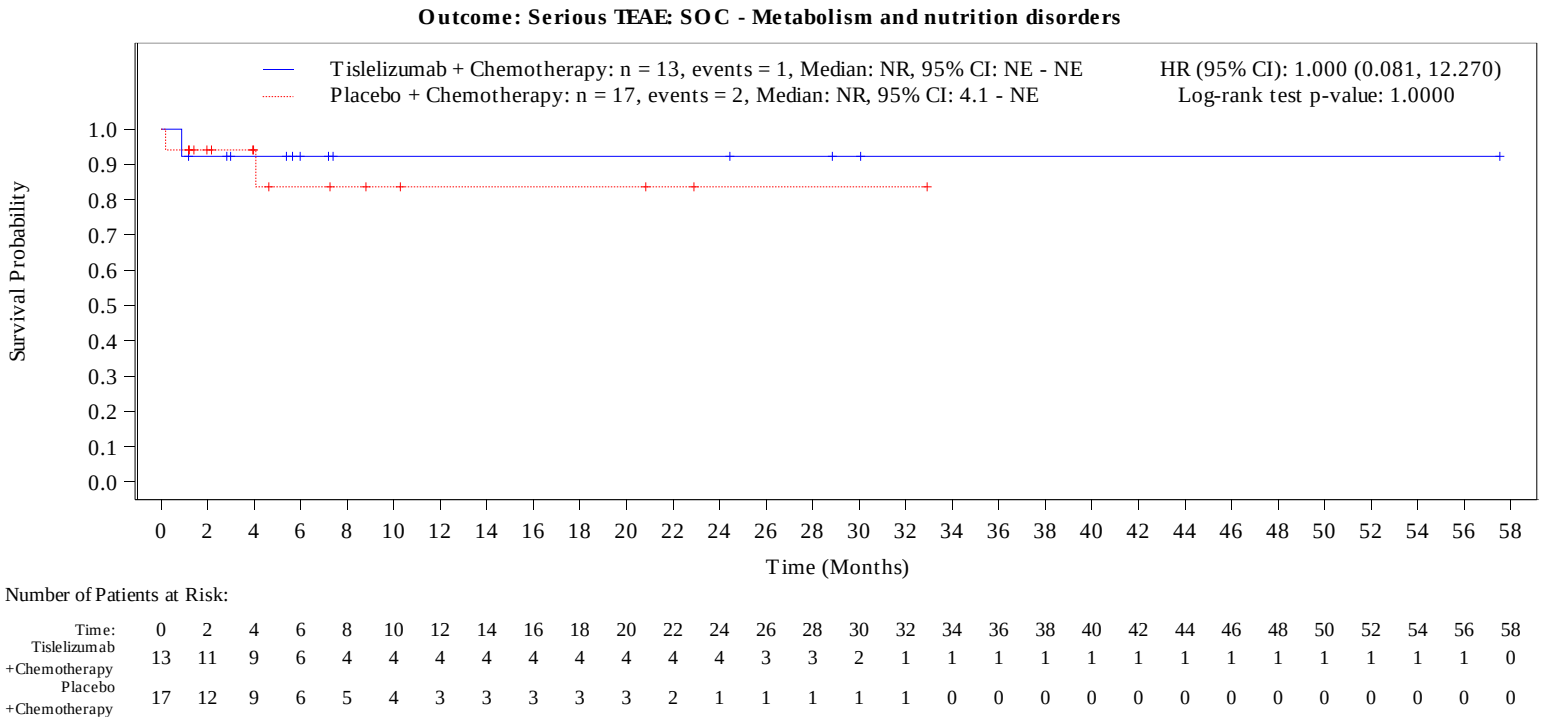
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-aesocpt.sas 14NOV2024 06:03 f-14-3-1-4-km-aesocpt-ser-pop1-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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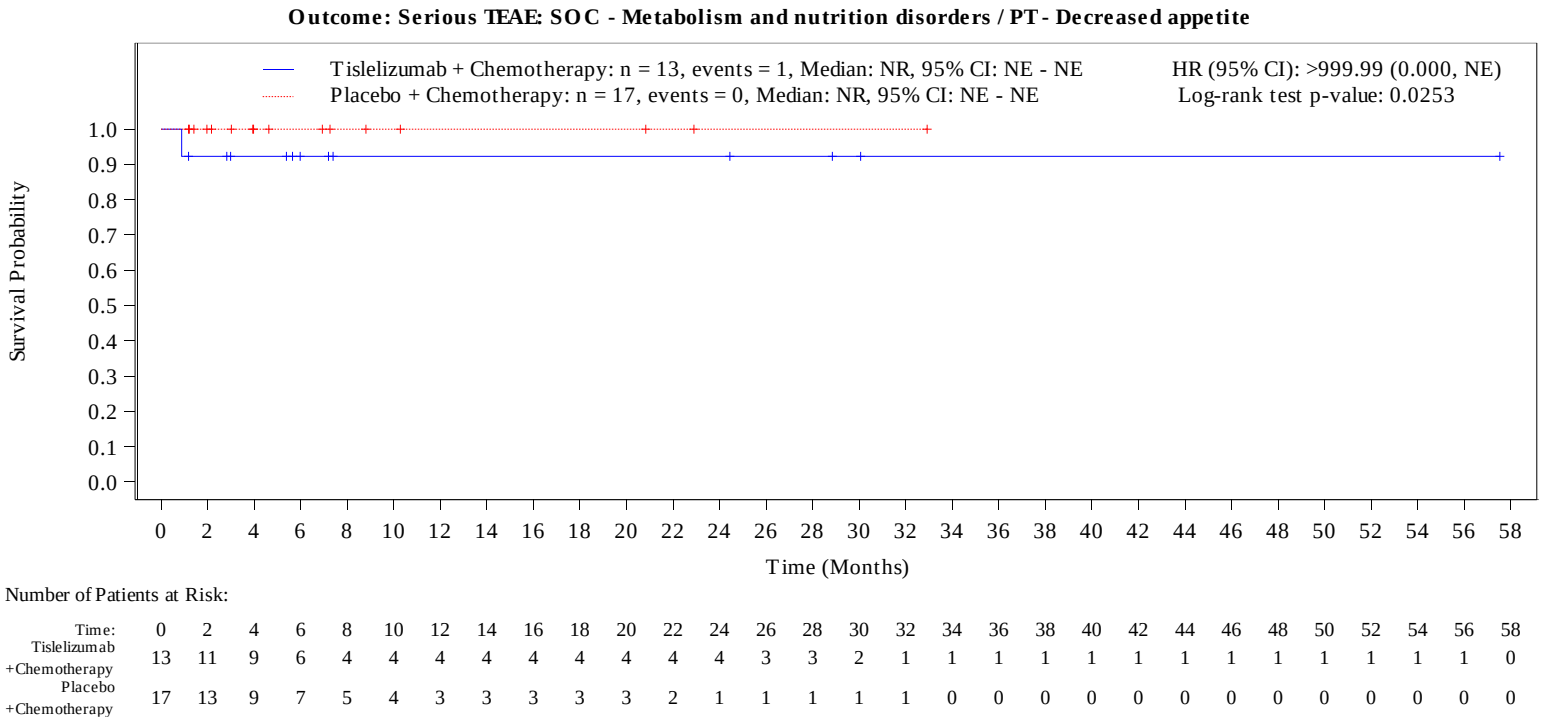
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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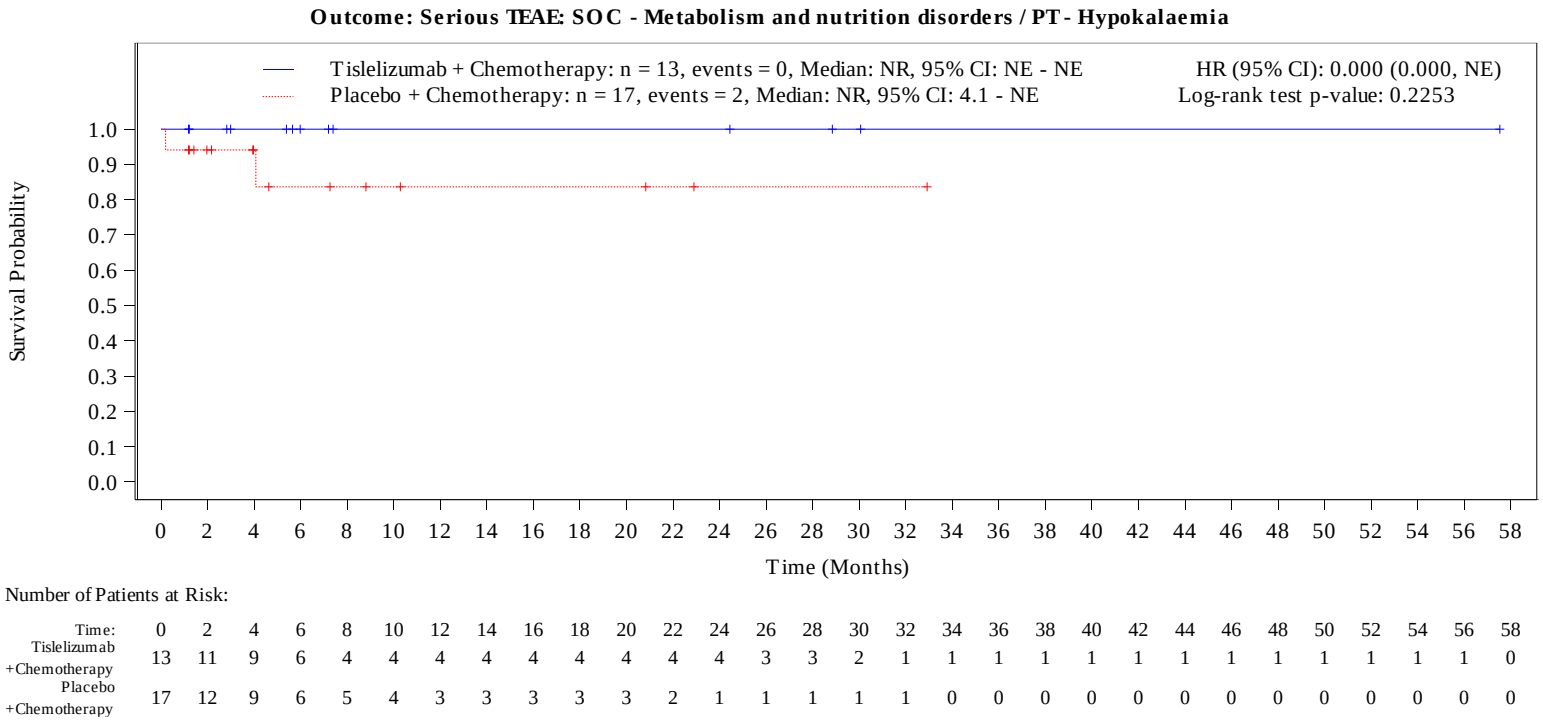
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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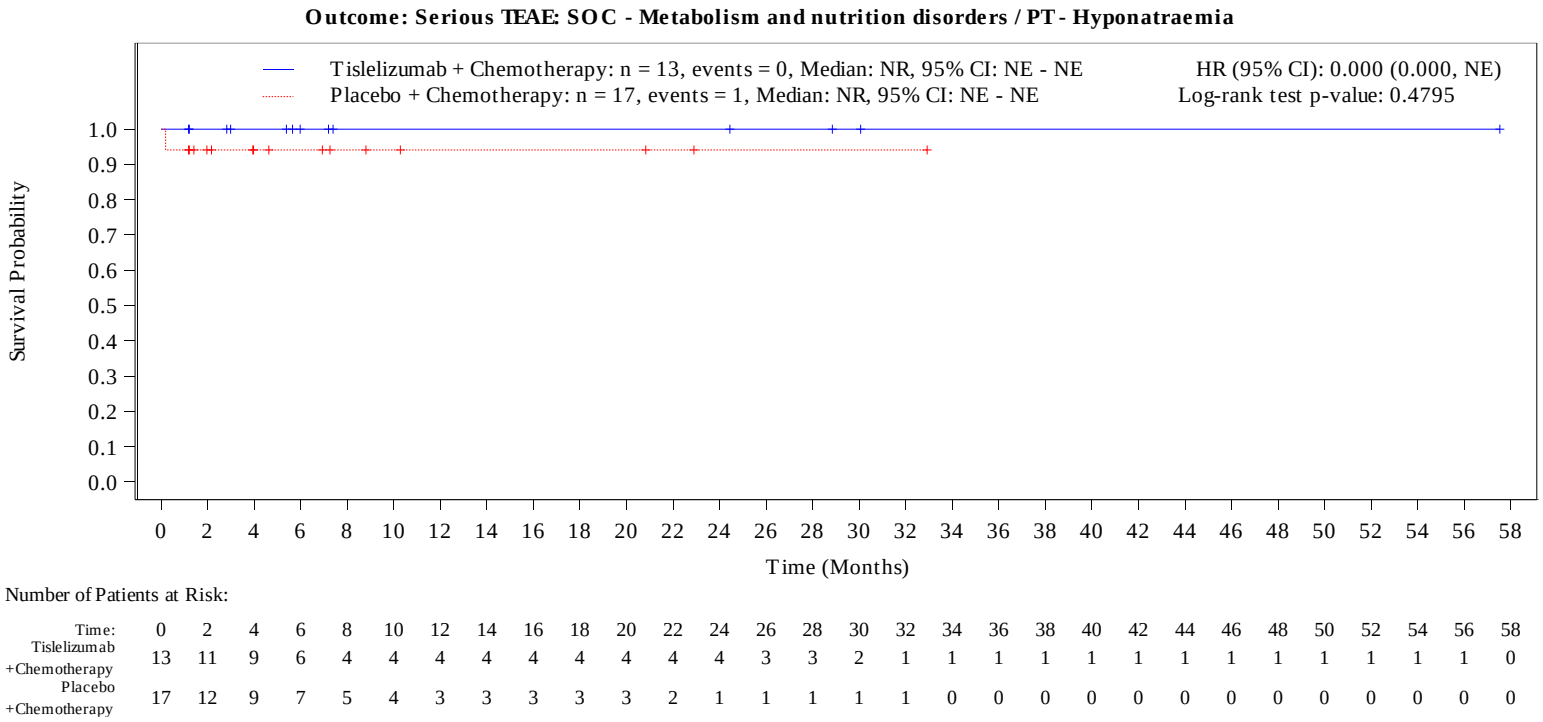
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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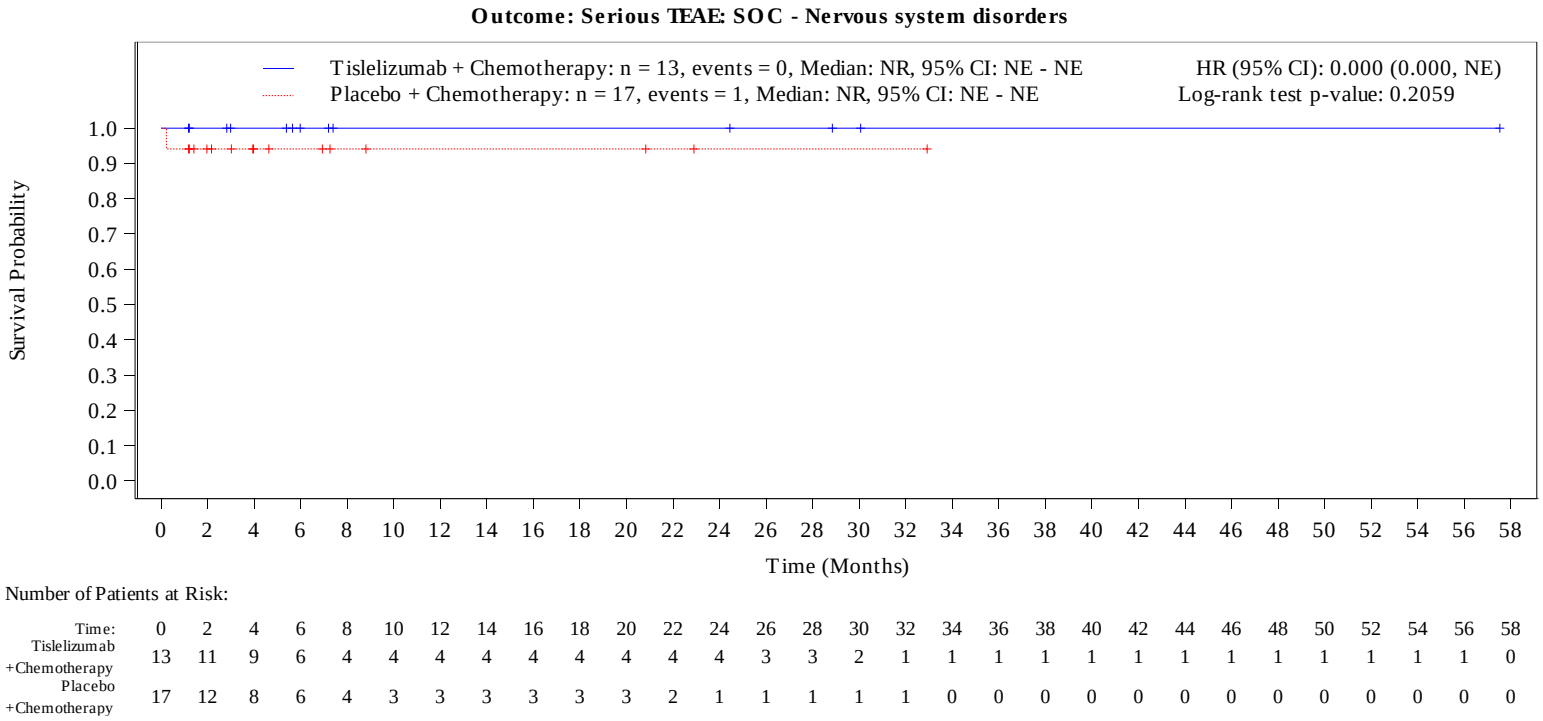
unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/f-km-aesocpt.sas 14NOV2024 06:03 f-14-3-1-4-km-aesocpt-ser-pop1-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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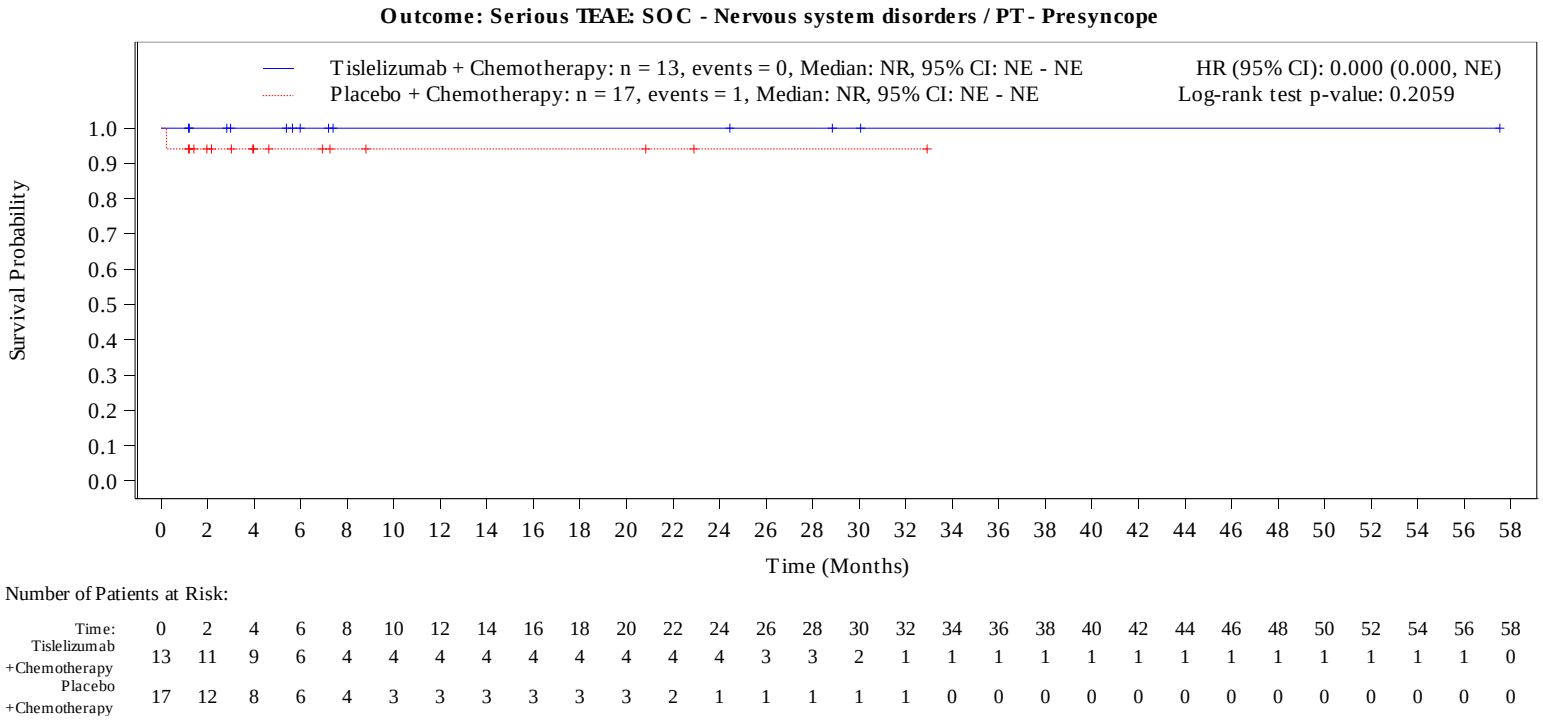
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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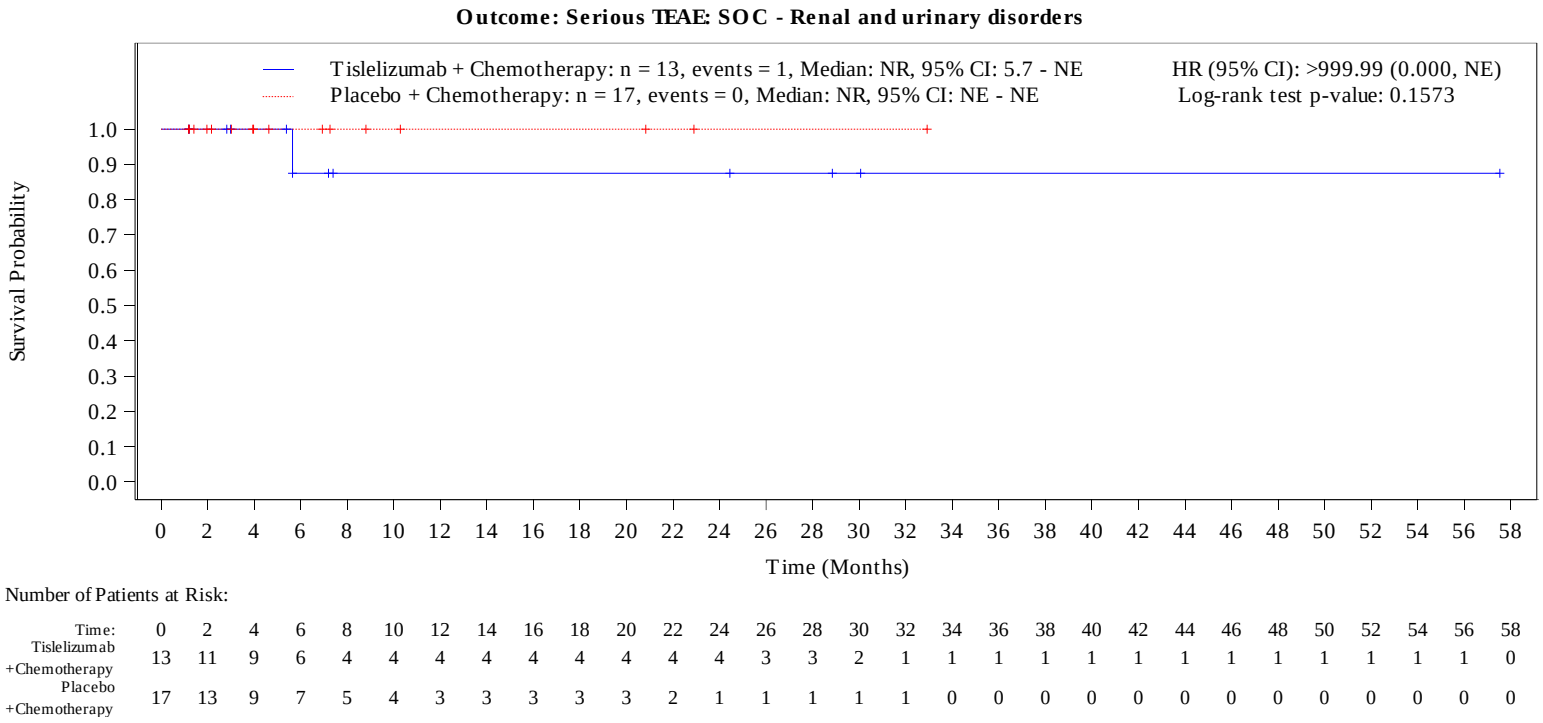
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



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Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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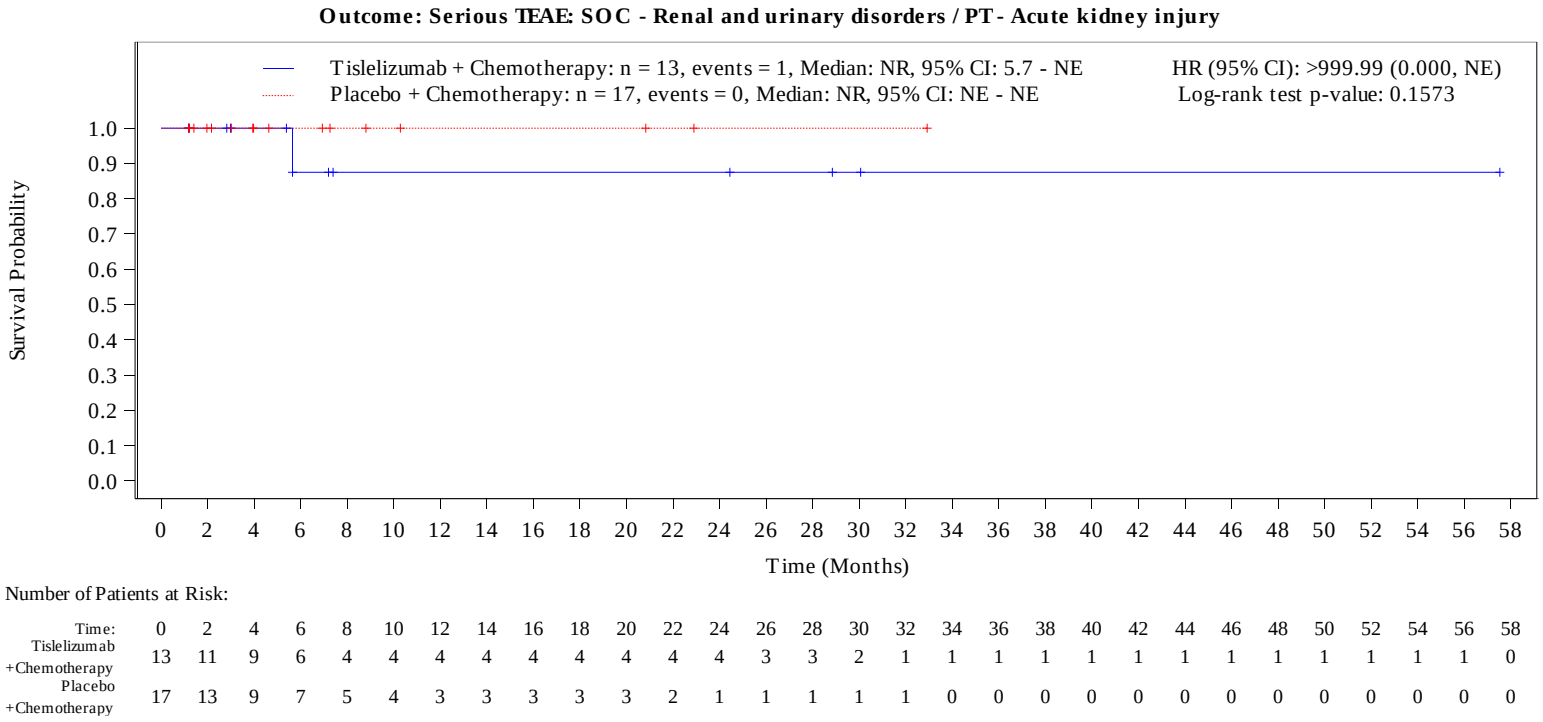
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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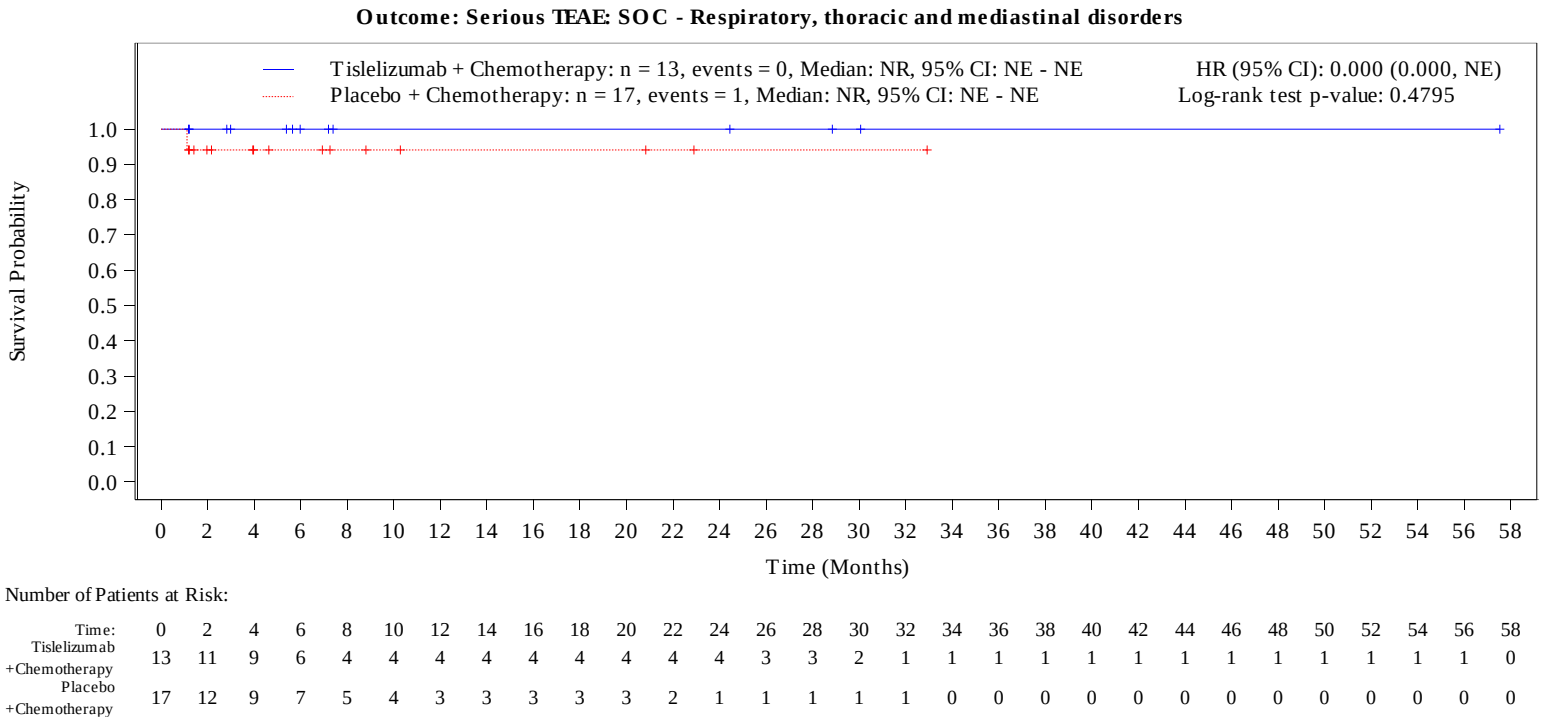
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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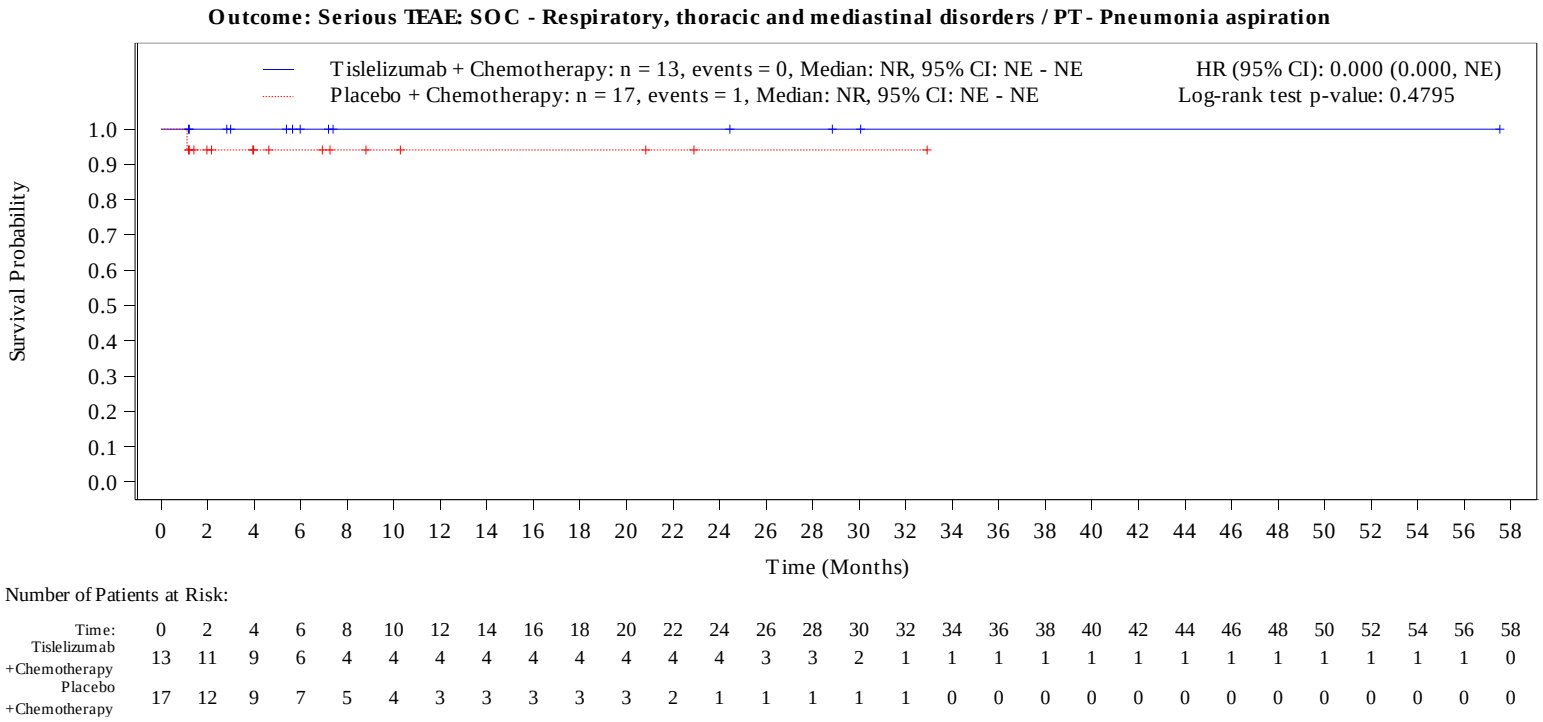
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	12	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	7 (77.8)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	6 (66.7)	--	11	3 (27.3)	--	--	--
Female	4	2 (50.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	2 (20.0)	--	--	--
1	6	5 (83.3)	--	7	2 (28.6)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	3 (75.0)	--	7	2 (28.6)	--	--	--
No	9	5 (55.6)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	4 (44.4)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	2 (22.2)	--	11	4 (36.4)	--	--	--
Female	4	2 (50.0)	--	6	2 (33.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	7	1 (14.3)	--	10	5 (50.0)	--	--	--
1	6	3 (50.0)	--	7	1 (14.3)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	2 (28.6)	--	--	--
No	9	4 (44.4)	--	10	4 (40.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	3 (37.5)	--	--	--
Age >= 65	4	0 (0.0)	--	9	6 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	0 (0.0)	--	11	5 (45.5)	--	--	--
Female	4	3 (75.0)	--	6	4 (66.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	6 (60.0)	--	--	--
1	6	3 (50.0)	--	7	3 (42.9)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any TEAE: SOC - Nervous system disorders

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	6 (85.7)	--	--	--
No	9	2 (22.2)	--	10	3 (30.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Lymphopenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	1 (25.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	2 (33.3)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	1 (25.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	2 (33.3)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
TEAE >= Grade 3: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0, and graded for severity using CTCAE v4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	1 (16.7)	--	7	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%
Serious TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: TEAE, treatment-emergent adverse event.

Adverse events were classified based on MedDRA v24.0.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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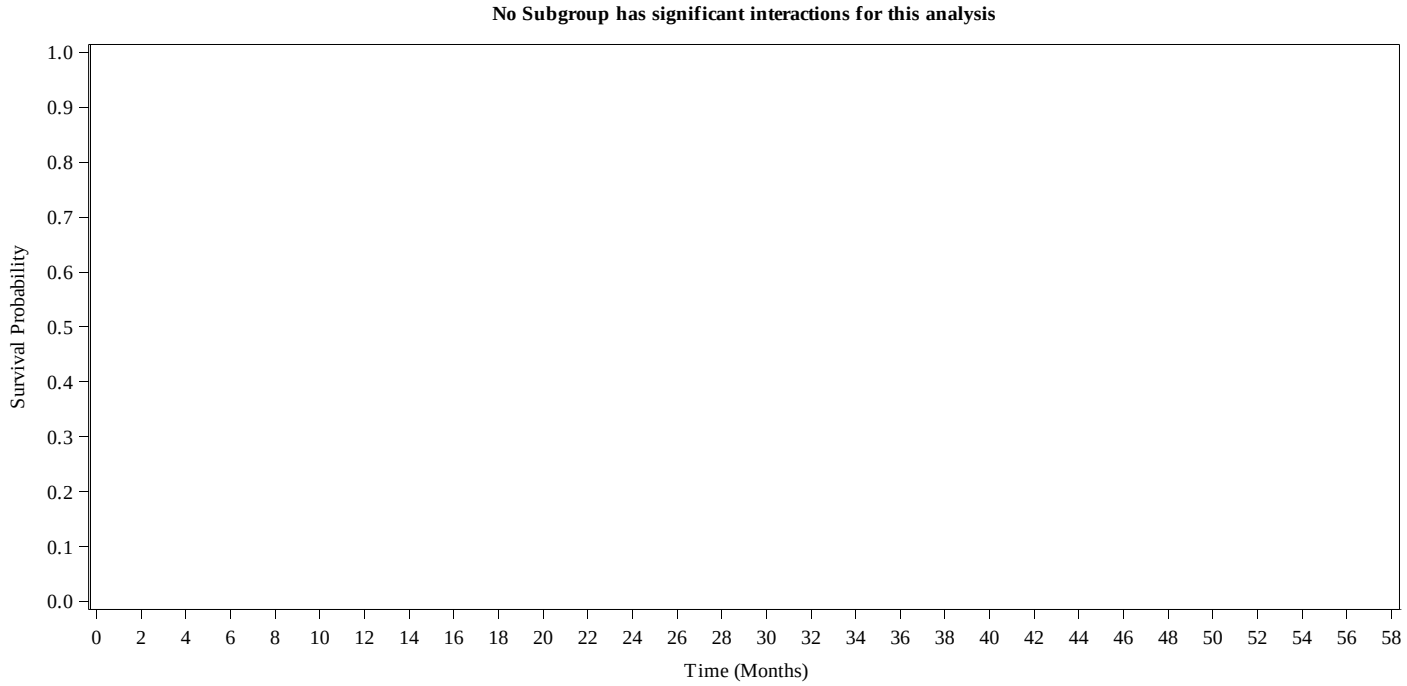
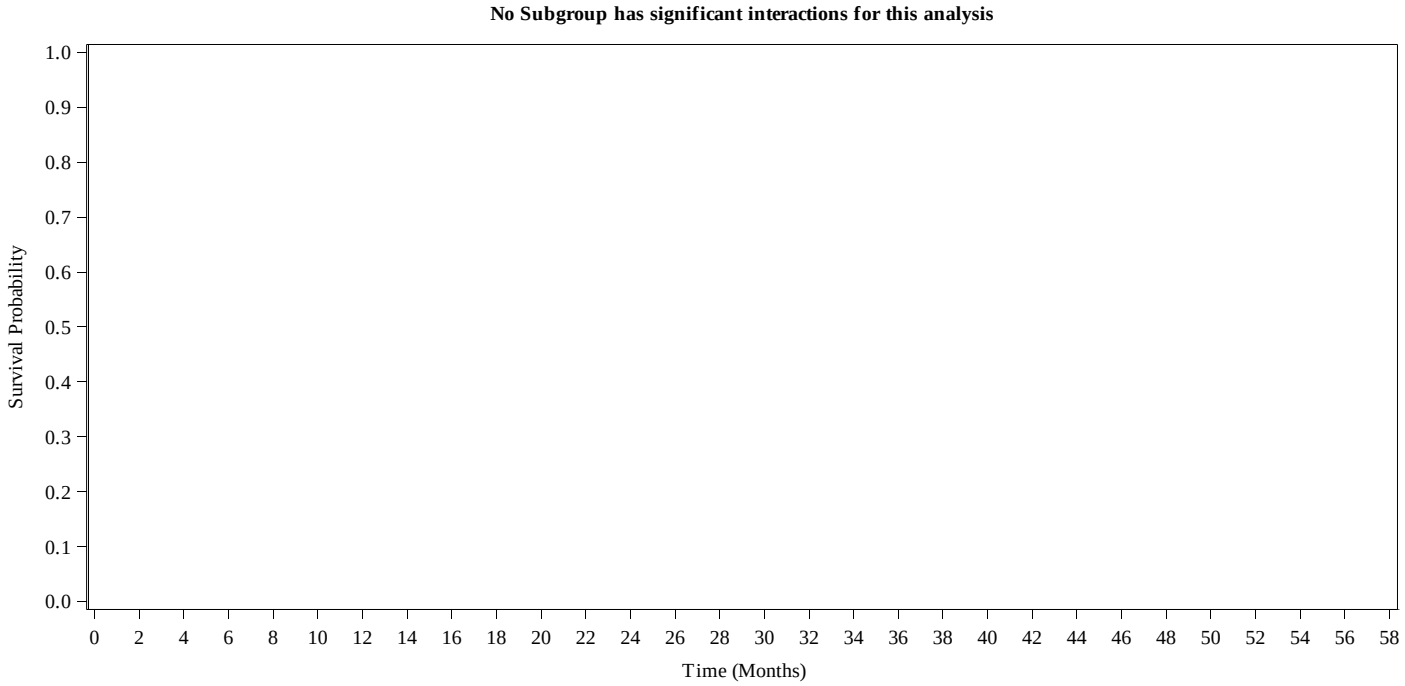
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



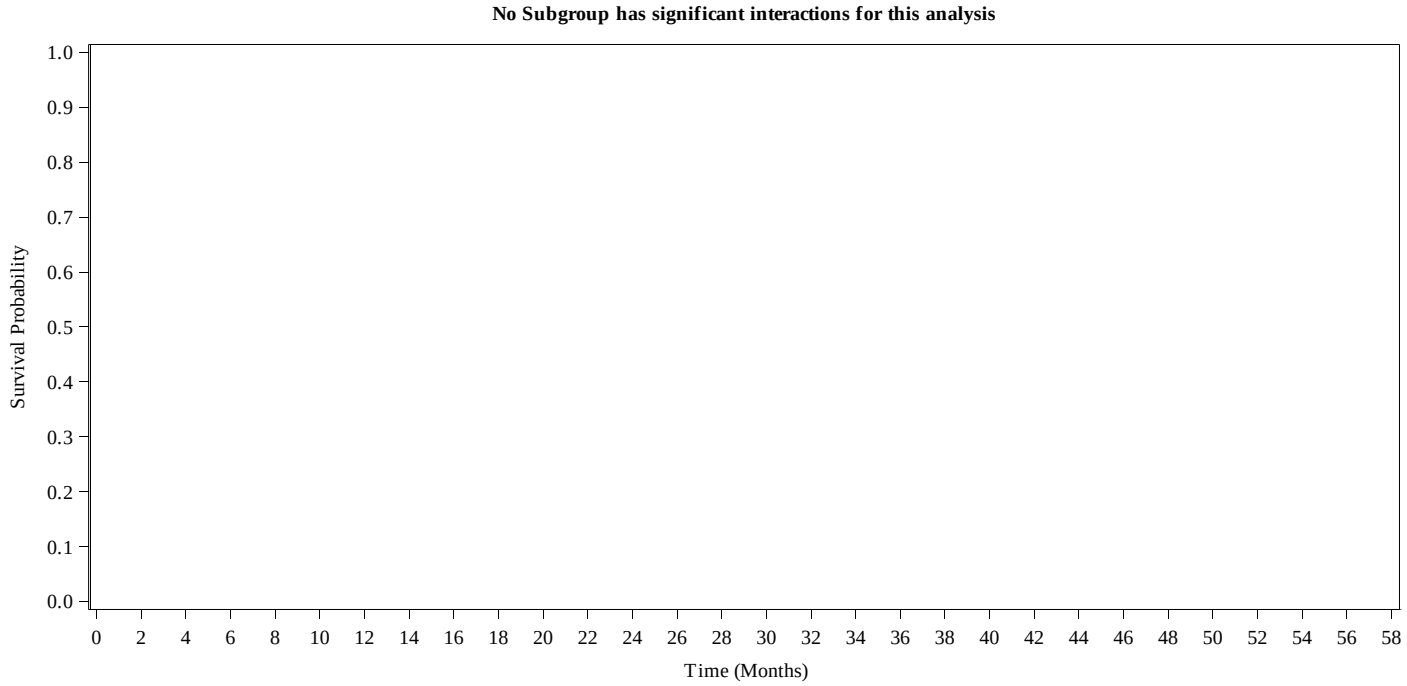
Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: TEAE, treatment-emergent adverse event. NE = not estimable; NR = not reached.
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.

Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any imAE	13	5 (38.5)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.186 (0.261, 5.396)	0.8252
imAE of Grade 1 and 2	13	4 (30.8)	NR (1.9, NE)	17	4 (23.5)	NR (8.3, NE)	1.081 (0.226, 5.165)	0.9220
imAE >= Grade 3	13	2 (15.4)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.1573
Serious imAE	13	1 (7.7)	NR (7.1, NE)	17	0 (0.0)	NR (NE, NE)	>999.99 (0.000, NE)	0.5930

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR of Grade 1 and 2	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
IRR >= Grade 3	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	13	0 (0.0)	NR (NE, NE)	17	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.

[c] P-value for treatment effect was based on a log rank test stratified by pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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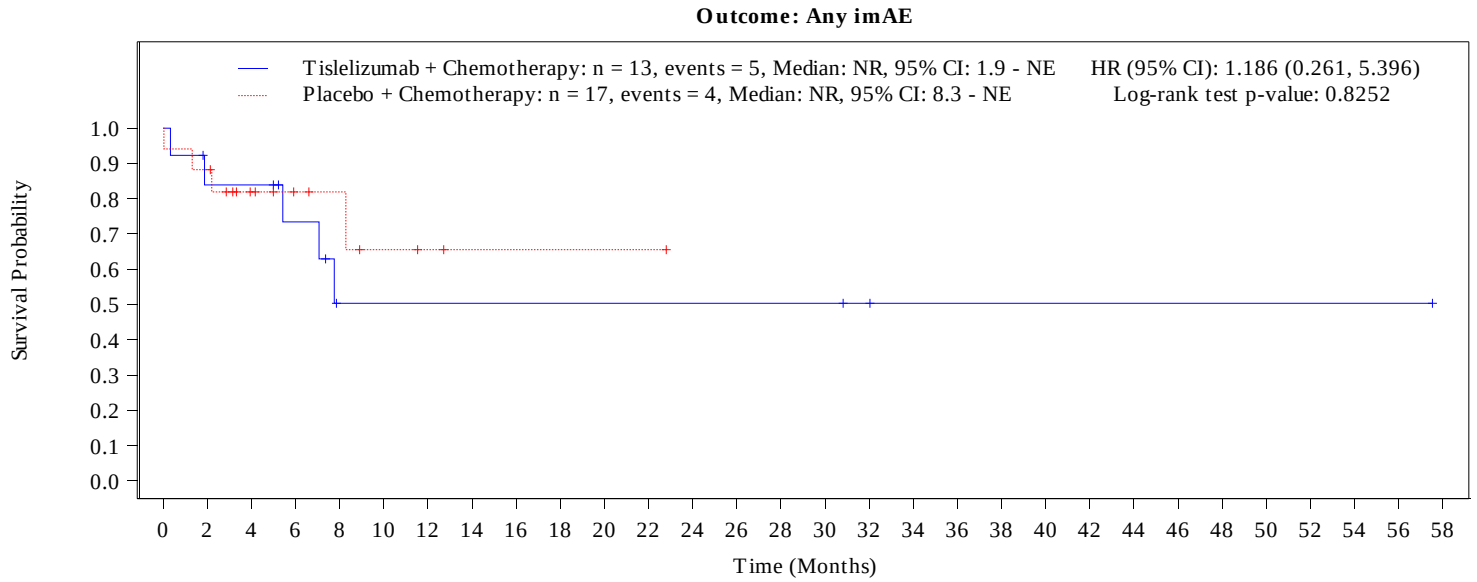
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	10	10	7	3	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	15	9	6	5	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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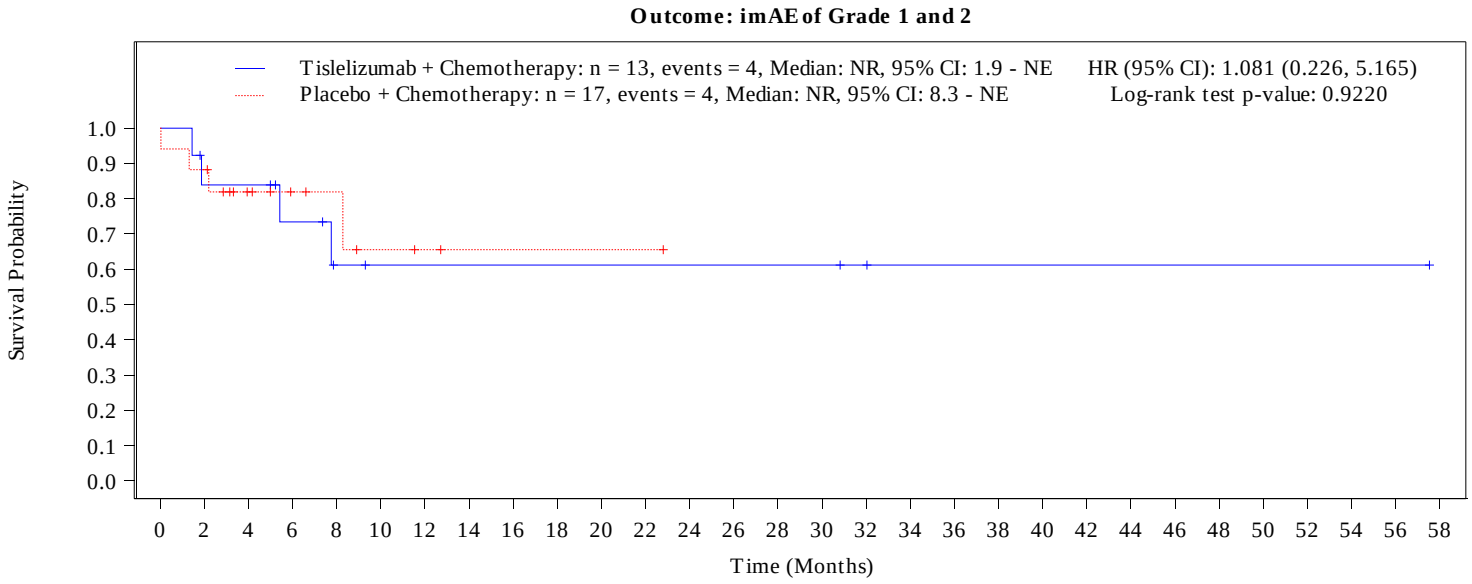
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	10	10	7	4	3	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	15	9	6	5	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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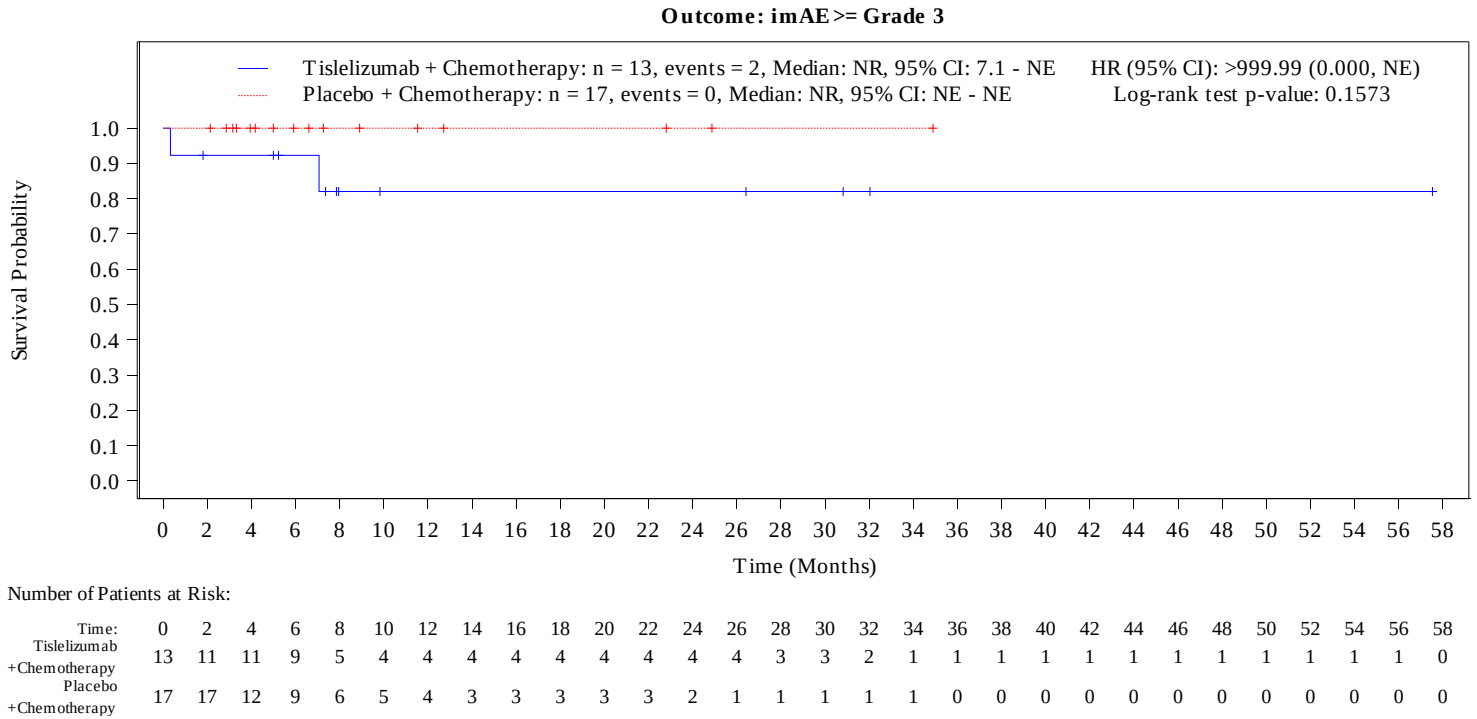
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	11	9	5	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	17	12	9	6	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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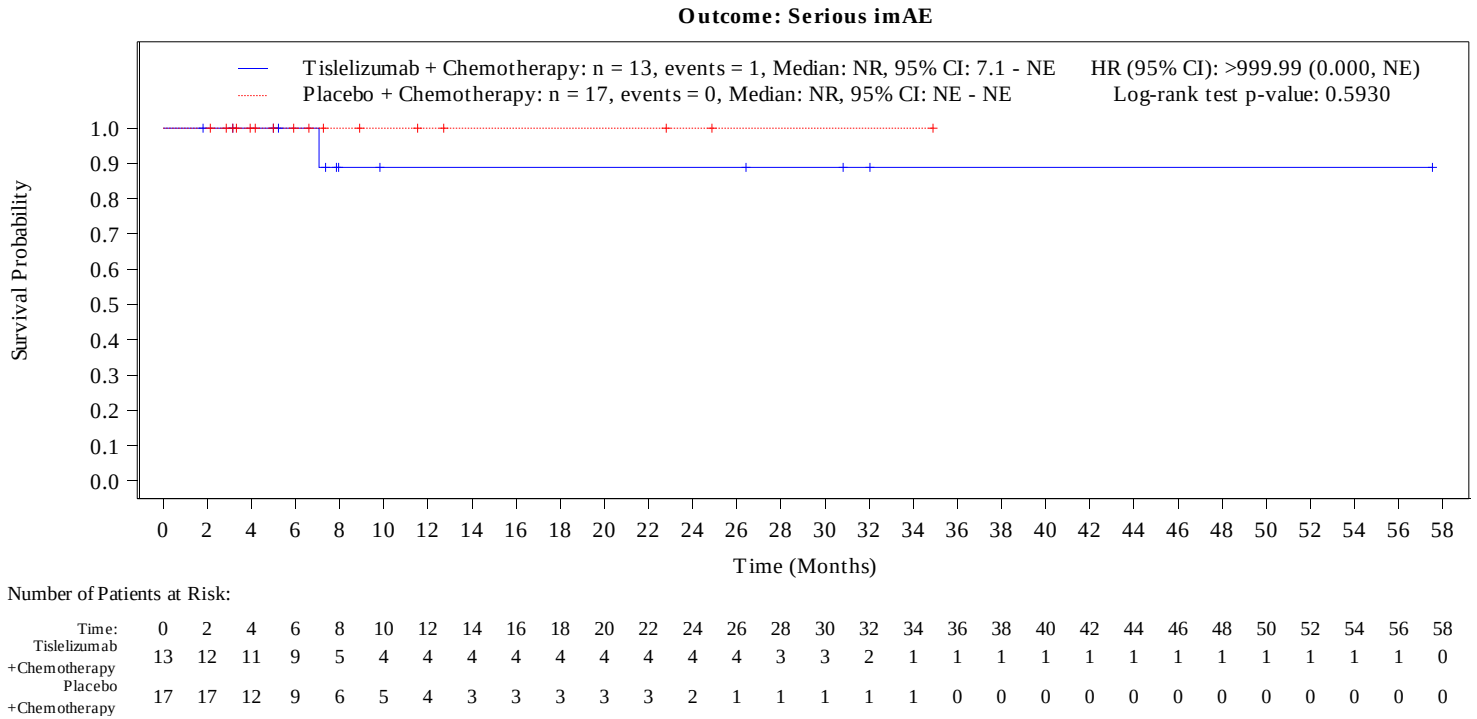
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	12	11	9	5	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	17	12	9	6	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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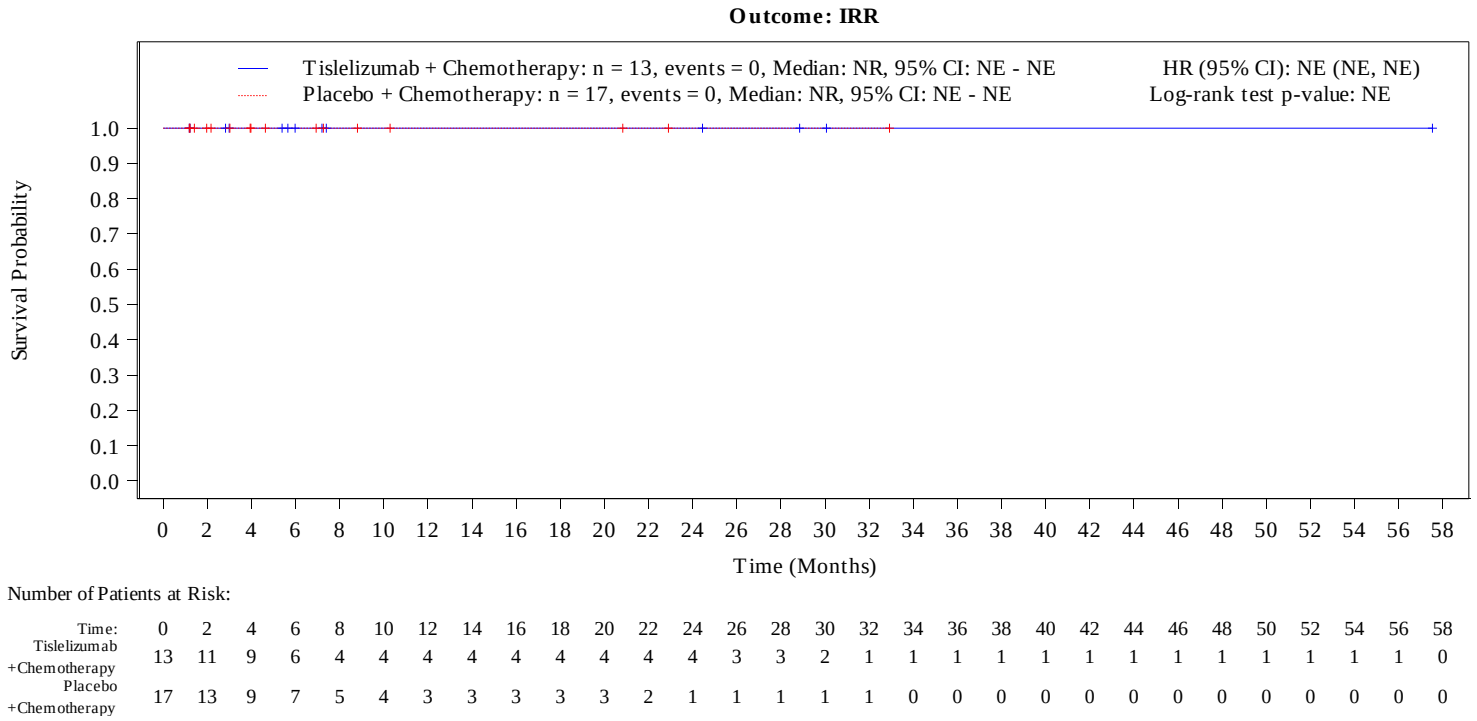
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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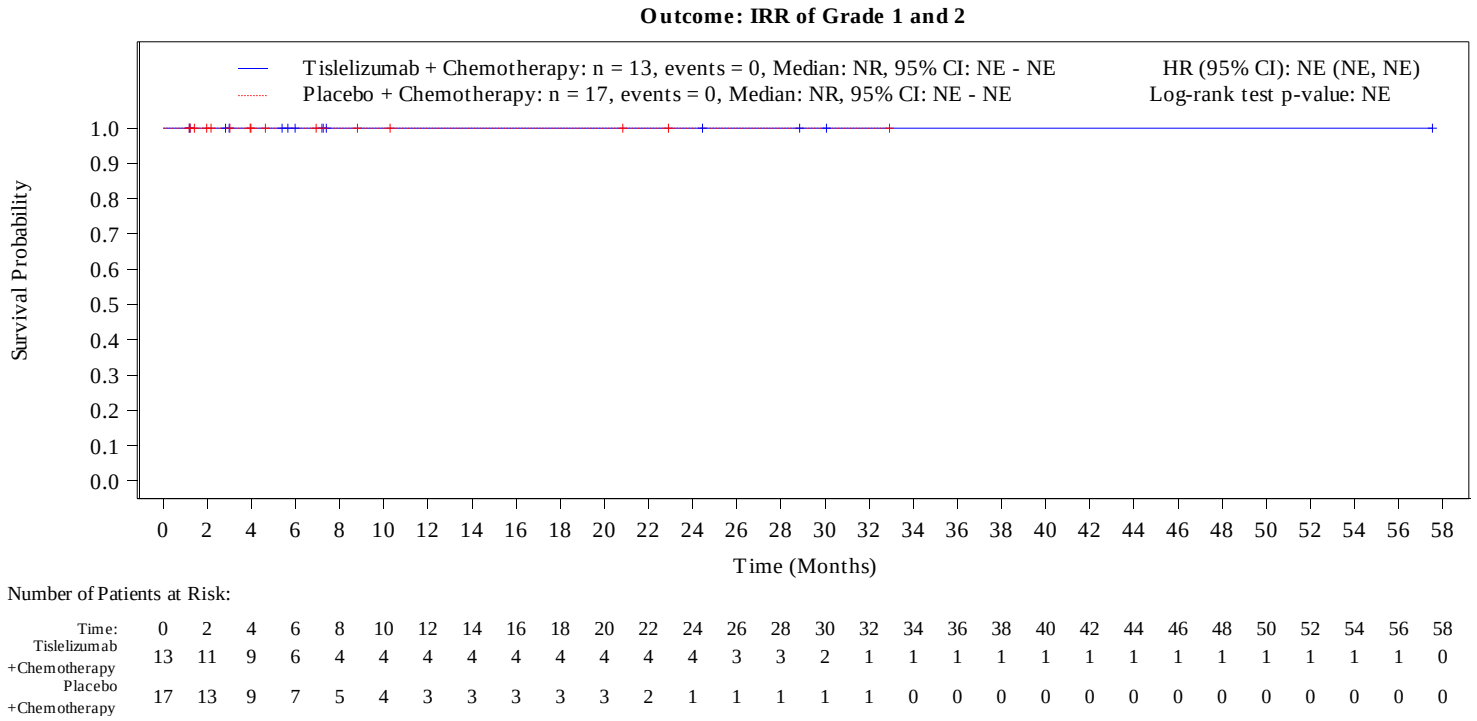
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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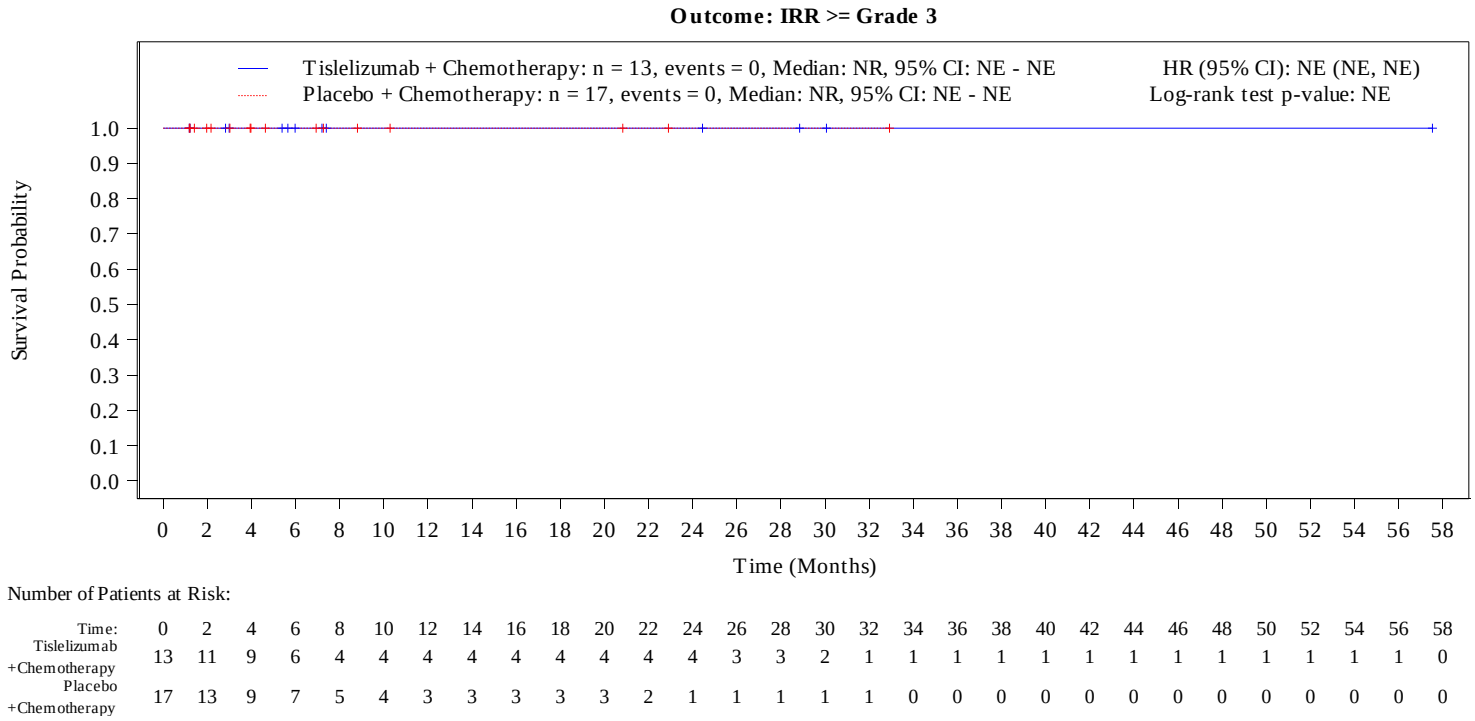
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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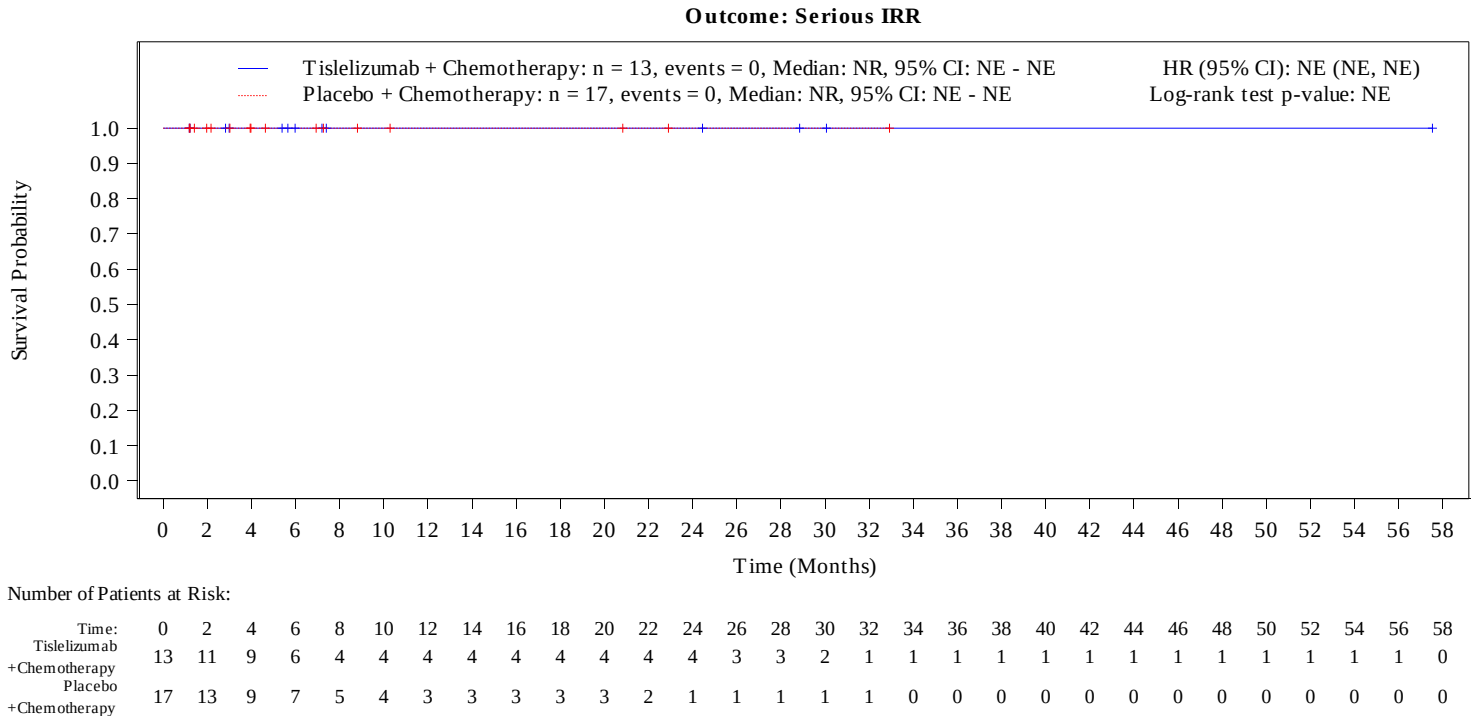
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58
Tislelizumab +Chemotherapy	13	11	9	6	4	4	4	4	4	4	4	4	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo +Chemotherapy	17	13	9	7	5	4	3	3	3	3	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Only patients receiving chemotherapy of Cisplatin and 5-FU are included. The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and pooled geographic region (Asia vs. Rest of World) per IRT, and prior definitive therapy (Yes vs. No) per IRT as strata.
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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	2 (50.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	4 (44.4)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Any imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	4 (57.1)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	3 (33.3)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	3 (33.3)	--	8	2 (25.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	2 (22.2)	--	--	--
Interaction								--
Sex								
Male	9	3 (33.3)	--	11	3 (27.3)	--	--	--
Female	4	1 (25.0)	--	6	1 (16.7)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	3 (42.9)	--	10	3 (30.0)	--	--	--
1	6	1 (16.7)	--	7	1 (14.3)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	2 (50.0)	--	7	2 (28.6)	--	--	--
No	9	2 (22.2)	--	10	2 (20.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

unblind/bgb_a317/bgb_a317_306/gba_2024q4_closeout/dev/pgm/tlfs/t-tte-aesi-subgrp.sas 14NOV2024 06:31 t-14-3-1-3-1-s-tte-aesi-subgrp-pop1-cl.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	1 (11.1)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	2 (22.2)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

imAE >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	2 (28.6)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	1 (25.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	1 (25.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	1 (11.1)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious imAE

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	1 (14.3)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	1 (11.1)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR of Grade 1 and 2

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

IRR >= Grade 3

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
Age < 65	9	0 (0.0)	--	8	0 (0.0)	--	--	--
Age >= 65	4	0 (0.0)	--	9	0 (0.0)	--	--	--
Interaction								--
Sex								
Male	9	0 (0.0)	--	11	0 (0.0)	--	--	--
Female	4	0 (0.0)	--	6	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%

Serious IRR

	Tislelizumab + Chemotherapy (N = 13)			Placebo + Chemotherapy (N = 17)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	7	0 (0.0)	--	10	0 (0.0)	--	--	--
1	6	0 (0.0)	--	7	0 (0.0)	--	--	--
Interaction								--
Prior Definitive Therapy per IRT								
Yes	4	0 (0.0)	--	7	0 (0.0)	--	--	--
No	9	0 (0.0)	--	10	0 (0.0)	--	--	--
Interaction								--

Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.

Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

Only patients receiving chemotherapy of Cisplatin and 5-FU are included.

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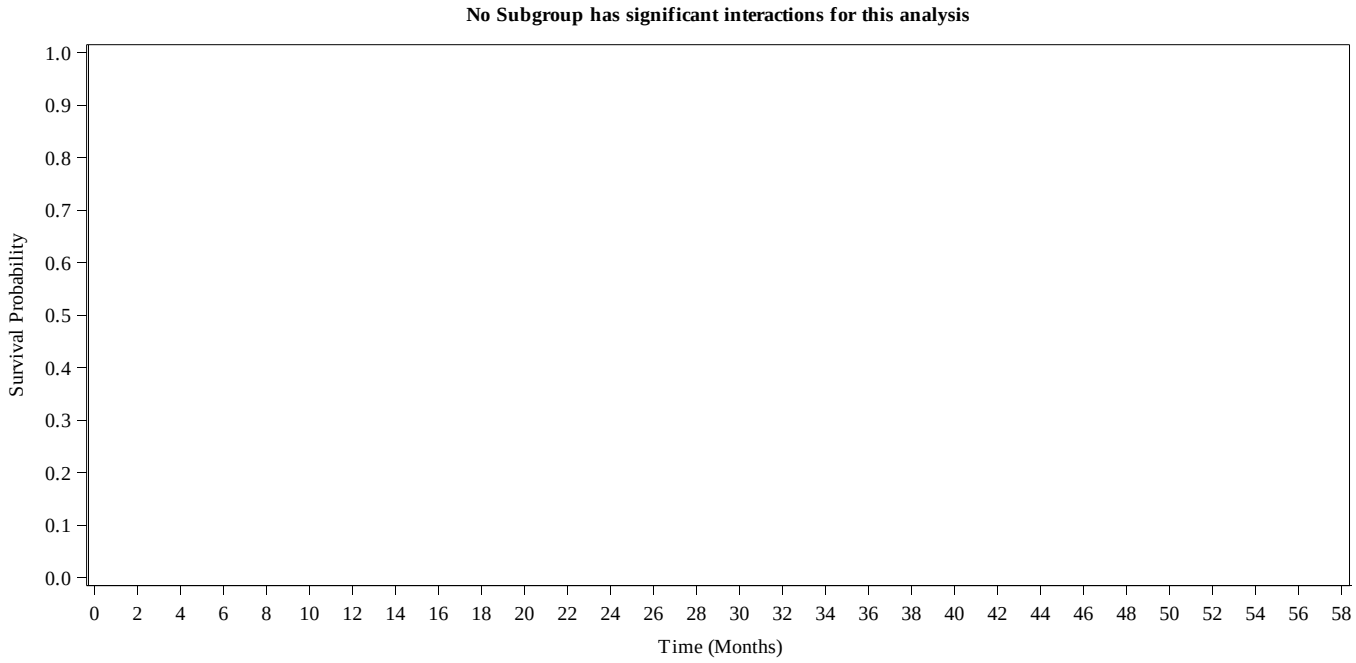
Figure 14.3.1.5.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation with PD-L1 Score < 10% & >= 5%



Source: ADTTEAE1. Study completion date (Last Patient Last Visit): 22AUG2024. Data extraction: 11OCT2024.
Abbreviations: imAE, immune-mediated adverse event; IRR, infusion-related reaction. NE = not estimable; NR = not reached
Adverse events were graded for severity using CTCAE v4.03. Only patients receiving chemotherapy of Cisplatin and 5-FU are included.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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